

LEGISLATIVE HEARING ON S. 544—HEALTH PLANNING  
AMENDMENTS OF 1979; S. 230—NURSE TRAINING  
AMENDMENTS OF 1979; AND S. 590—CLINICAL  
LABORATORY IMPROVEMENT ACT OF 1979

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HEARING  
BEFORE THE  
SUBCOMMITTEE ON  
HEALTH AND SCIENTIFIC RESEARCH  
OF THE  
COMMITTEE ON  
LABOR AND HUMAN RESOURCES  
UNITED STATES SENATE

NINETY-SIXTH CONGRESS

FIRST SESSION

ON

**S. 544**

TO AMEND TITLES XV AND XVI OF THE PUBLIC HEALTH  
SERVICE ACT TO REVISE AND EXTEND THE AUTHORITIES  
AND REQUIREMENTS UNDER THOSE TITLES FOR HEALTH  
PLANNING AND HEALTH RESOURCES DEVELOPMENT

**S. 230**

TO AMEND TITLE VIII OF THE PUBLIC HEALTH SERVICE ACT  
TO EXTEND THROUGH FISCAL YEAR 1980 THE PROGRAM OF  
ASSISTANCE FOR NURSE TRAINING, AND FOR OTHER  
PURPOSES

**S. 590**

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REVISE  
AND STRENGTHEN THE PROGRAM UNDER THAT ACT FOR THE  
REGULATION OF CLINICAL LABORATORIES

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MARCH 16, 1979



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MARCH 16, 1979



Printed for the use of the Committee on Labor and Human Resources

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# CONTENTS

Text of:	Page
S. 544 .....	4
S. 230 .....	61
S. 590 .....	70

## CHRONOLOGICAL LIST OF WITNESSES

FRIDAY, MARCH 16, 1979

Richmond, Julius B., M.D., Assistant Secretary for Health and Surgeon General, accompanied by Henry Foley, Ph. D., Administrator, Health Resources Administration; Martin Baum, Ph. D., Special Assistant to the Deputy Assistant Secretary for Health (Planning and Evaluation); Edward Kelly, Deputy Director, Bureau of Health Standards and Quality, Health Care Financing Administration; Carol Emmott, Ph. D., Special Assistant, Office of the Deputy Assistant Secretary for Legislation (Health) .....	114
Wilder, B. J., M.D., professor of medicine (neurology), University of Florida, College of Medicine; accompanied by Brenta Davis, M. Ed., associate professor, clinical laboratory sciences, University of Tennessee, Center for the Health Sciences; William Hausler, Ph. D., director of laboratory division, Iowa State Health Department; Katherine O'Reilly, executive director, Consumer Federation of America .....	187
Weary, Peyton E., M.D., American Academy of Dermatology .....	195
Densmore, William P., vice president, Norton Co., Worcester, Mass., board member of Central Massachusetts Health Systems Agency; accompanied by Jacqueline B. Hanson, president-elect, American Health Planning Association, and immediate past president of Mid-America Health Systems Agency; and Harry P. Cain, Ph. D., executive director, American Health Planning Association .....	231
Clifford, Joyce C., R.N., director of nursing services, Beth Israel Hospital, Boston, Mass.; accompanied by Doris Blaney, Ed. D., R.N., member, ANA Commission on Nursing Education, and professor and chairperson, Division of Nursing, Indiana University Northwest, Gary Ind.; Linda K. Amos, Ed. D., FAAN, for American Association of Colleges of Nursing, dean and professor, School of Nursing, Boston University; Anna B. Coles, Ph. D., R.N., for National League of Nursing, dean, College of Nursing, Howard University; and Connie Brotemarkle, president, Student Nurses' Association, undergraduate student, George Mason University .....	305

## STATEMENTS

American Academy of Dermatology, Peyton E. Weary, M.D., on behalf of, prepared statement .....	210
American Health Planning Association, Jacqueline B. Hanson, president-elect, William P. Densmore, consumer board member, Central Massachusetts Health Systems Agency, and Harry P. Cain II, Ph. D., executive director, prepared statement .....	240

Clifford, Joyce C., R.N., director of nursing services, Beth Israel Hospital, Boston, Mass.; accompanied by Doris Blaney, Ed. D., R.N., member, ANA Commission on Nursing Education, and professor and chairperson, Division of Nursing, Indiana University Northwest, Gary, Ind.; Linda K. Amos, Ed. D., FAAN, for American Association of Colleges of Nursing, dean and professor, School of Nursing, Boston University; Anna B. Coles, Ph. D., R.N., for National League of Nursing, dean, College of Nursing, Howard University; and Connie Brotemarkle, president, Student Nurses' Association, undergraduate student, George Mason University .....	305
Densmore, William P., vice president, Norton Co., Worcester, Mass., board member of Central Massachusetts Health Systems Agency; accompanied by Jacqueline B. Hanson, president-elect, American Health Planning Association, and immediate past president of Mid-America Health Systems Agency; and Harry P. Cain, Ph. D., executive director, American Health Planning Association .....	231
Epilepsy Foundation of America, B. J. Wilder, M.D., representing the, prepared statement .....	190
Hatch, Hon. Orrin G., a U.S. Senator from the State of Utah, prepared statement .....	113
Javits, Hon. Jacob K., a U.S. Senator from the State of New York, prepared statement .....	110
Richmond, Julius B., M.D., Assistant Secretary for Health and Surgeon General; accompanied by Henry Foley, Ph. D., Administrator, Health Resources Administration; Martin Baum, Ph. D., Special Assistant to the Deputy Assistant Secretary for Health (Planning and Evaluation); Edward Kelly, Deputy Director, Bureau of Health Standards and Quality, Health Care Financing Administration; Carol Emmott, Ph. D., Special Assistant, Office of the Deputy Assistant Secretary for Legislation (Health) .....	114
Prepared statement .....	122
Weary, Peyton E., M.D., American Academy of Dermatology .....	195
Prepared statement .....	210
Wilder, B. J., M.D., professor of medicine (neurology), University of Florida, College of Medicine; accompanied by Brenta Davis, M. Ed., associate professor, clinical laboratory sciences, University of Tennessee, Center for the Health Sciences; William Hausler, Ph. D., director of laboratory division, Iowa State Health Department; Katherine O'Reilly, executive director, Consumer Federation of America .....	187
Prepared statement .....	190

#### ADDITIONAL INFORMATION

Articles, publications, etc.:	
Excerpt from Senate bill S. 590, section 370, pages 3-4 .....	223
National Coalition for CLIA Participating Organizations .....	218
Synopsis and proceedings of the council meeting, May 18, 1977, from the Massachusetts Medical Society .....	199
Communications to:	
Javits, Hon. Jacob K., a U.S. Senator from the State of New York, from Peyton E. Weary, M.D., chairman, council on governmental liaison, American Academy of Dermatology, Inc., Charlottesville, Va., March 19, 1979 (with attachment) .....	225
Selected charts:	
Admissions to nursing schools have increased .....	174
On balance, by 1985 the aggregate supply of nurses will fall within the range of aggregate demand .....	175

#### APPENDIX

Statements submitted for the record on S. 544:	
American Clinical Laboratory Association, prepared statement .....	311
American Dental Association, William E. Allen, D.D.S., chairman, council on legislation, prepared statement .....	324
American Hospital Association, prepared statement .....	330
American Hospital Association, prepared statement .....	381
American Medical Association, prepared statement .....	400
American Osteopathic Hospital Association, prepared statement .....	417
American Psychiatric Association, prepared statement .....	455

	Page
Association of American Medical Colleges, prepared statement .....	457
Association of Rehabilitation Facilities, prepared statement .....	471
Blue Cross and Blue Shield Associations, prepared statement .....	475
Health Insurance Association of America, prepared statement .....	497
Health Advocates, Inc., Samuel M. Levine, JD, president, prepared statement .....	507
Minnesota Health Systems Agency Six, Bjorn Larsen, executive director, prepared statement .....	528
National Association of Counties, Bernard F. Hellenbrand, executive director, prepared statement .....	531
National Conference of State Legislatures, prepared statement .....	551
National Council on Health Planning and Development, Sally Berger, chairman, prepared statement .....	553
Puget Sound Council of Governments, Lorraine Hine, president, prepared statement .....	555
Service Employees International Union, AFL-CIO, prepared statement ....	556
Washington Business Group on Health, Willis B. Goldbeck, director, prepared statement .....	562
Department of Health and Social Services, State of Wisconsin, prepared statement .....	564
Statements submitted for the record on S. 230:	
American Nurses' Association, Joyce C. Clifford, R.N., M.S.N., assistant director, and director of nursing services, Beth Israel Hospital, Boston, on behalf of, prepared statement .....	567
National League for Nursing, prepared statement .....	573
American Association of Colleges of Nursing, Linda K. Amos, R.N., Ed. D., dean, Boston University School of Nursing, on behalf of, prepared statement .....	578
National Student Nurses' Association, Inc., Connie Brotemarkle, president, Student Nurses' Association of Virginia, on behalf of, prepared statement .....	584
American Association of Nurse Anesthetists, prepared statement .....	591
American Medical Association, James H. Sammons, M.D., executive vice president, prepared statement .....	599
Virginia Nurses' Association, prepared statement .....	601
American Psychiatric Association, Jules H. Masserman, M.D., president, prepared statement .....	602
South Dakota Association of Nurse Anesthetists, Joseph A. George, chairman, government relations committee, prepared statement .....	606
Statements submitted for the record on S. 590:	
American Society of Clinical Pathologists, prepared statement .....	607
American Hospital Association, prepared statement .....	615
Joint Commission on Accreditation of Hospitals, John E. Affeldt, M.D., president, prepared statement .....	625
College of American Pathologists, prepared statement .....	638
American Society of Anesthesiologists, Society of Academic Anesthesia, Chairmen, and the Society of Critical Care Medicine, Jerome H. Modell, M.D., on behalf of, prepared statement .....	657
American Association for Clinical Chemistry, Albert A. Dietz, Ph. D., prepared statement .....	677
Sheekey, Kathleen D., information director, Consumer Federation of America, prepared statement .....	691
American Medical Technologists, prepared statement .....	699
American Medical Association, prepared statement .....	721
American Federation of Labor and Congress of Industrial Organizations, prepared statement .....	732
American Clinical Laboratory Association, prepared statement .....	737
Consumer Federation of America, prepared statement .....	745
New York State Health Department, prepared statement .....	553



# LEGISLATIVE HEARING ON S. 544—HEALTH PLANNING AMENDMENTS OF 1979; S. 230— NURSE TRAINING AMENDMENTS OF 1979; AND S. 590—CLINICAL LABORATORY IMPROVE- MENT ACT OF 1979

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FRIDAY, MARCH 16, 1979

U.S. SENATE,  
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES,  
*Washington, D.C.*

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 4232, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Schweiker, and Javits.

Staff members present: Robert Wenger, Stuart Shapiro, and Christine Burch, professional staff; and John Rother and Dan Bourque, minority staff.

## OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. We will be in order.

This morning we will hear testimony on three pieces of legislation: S. 544, the Health Planning Amendments of 1979; S. 230, the Nurse Training Amendments of 1979; and S. 590, the Clinical Laboratories Improvement Act of 1979. Similar legislation to all three unanimously passed the Senate in the 95th Congress but failed to be enacted into law.

The Health Planning Amendments of 1979, which I introduced last week along with Senator Schweiker and several of my colleagues, build on and strengthen the National Health Planning and Resource Development Act of 1974 and should help us achieve a rational system of health planning so that every American will be able to receive quality care at a reasonable cost.

I know of no greater opportunity this Congress will have early in its first session to improve and support one of the most impressive cost containment programs in the health field: the very effective local and State planning effort.

The 205 health systems agencies and 56 State health planning agencies which seem to make a good conceptual sense when authorized 4 years ago are now vividly demonstrating their work in containing costs and allocating resources. As we discovered in the extensive hearings on this legislation last year, the practice of

health planning is maturing, and we now have enough data to document its positive impact.

Last year this subcommittee held comprehensive hearings on health planning and developed legislation after soliciting the views of over 400 organizations and individuals.

In July of 1978, the full Senate debated the planning bill on the floor, accepted some good amendments, and by a unanimous vote passed S. 2410, The Health Planning Amendments of 1978.

Unfortunately, in the heavy crush of business at the conclusion of the last Congress, the House was not able to consider the companion bill to S. 2410, and thus the renewal process was carried over to this Congress.

S. 544 is very similar to the bill that passed the Senate last July except for modifications which include changes in relevant dates and in the requirement for State certificate-of-need programs regarding the acquisition of expensive medical equipment.

The bill is intended to support and extend the basic character and structure of the health planning program. The bill contains a number of provisions that will strengthen the role of consumers and Governors alike and better integrates health planning with mental health planning. As the program is maturing, we should be very wary of changes that would substantially disrupt it.

Prompt enactment of this legislation is a compelling matter, not simply to avoid unnecessary confusion at the state level and with State legislatures, but more importantly because the best means we now have must be applied to combat the astounding increases in health care costs and to assure that all Americans will have access to high quality health care.

The American Health Planning Association, which will testify before us today, has done an extensive survey of the planning agency and will present evidence that the health planning program is an extraordinary cost-effective program in reducing the escalating costs of health care in the United States.

The Nurse Training Amendments of 1979, introduced in January with Senator Javits as the principal sponsor, extends through fiscal year 1980 the Federal support of nurse education and training.

Last year the Congress sent to the President similar legislation which was pocket vetoed despite having passed the Senate unanimously and the House by a vote of 393 to 12. I was disappointed the President pocket vetoed the bill.

I do not believe the citizens of this nation, who are having desperate trouble finding enough nurses to staff their hospitals, believe that we have too many nurses or that we ought to train less.

We will hear today of nursing administrators doing active recruiting and of cities holding job fairs to attract nurses. We have seen newspaper articles across the country attesting to the shortage.

The bill we are now considering S. 230, was introduced by Senator Javits and now has the cosponsorship of 29 members of the Senate. It is a 1-year extension. It authorizes \$125 million for fiscal year 1980.

The simple 1-year extension is for two reasons. First, it will permit completion of a study by the Institute of Medicine assessing



the nursing supply in this country. Second, it will bring nurse training in line with the review of all the other manpower programs authorized under Public Law 94-484, which expires at the end of fiscal year 1980.

The last bill we will consider at this morning's hearing is S. 590, the Clinical Laboratory Improvement Act of 1979. S. 590 is substantially similar to the bill that unanimously passed the Senate in the 95th Congress but failed to get scheduled for floor action in the House in the hectic final days of the last Congress.

Senator Javits is once again the sponsor of this legislative endeavor. For over a decade, Senator Javits has been leading the fight to improve the quality of the performance of our Nation's clinical laboratories which is so vital to our health care system.

The clinical laboratory industry now costs the American people over \$12 billion dollars a year. By next year, some \$8.8 billion clinical laboratory tests will be conducted at a cost of \$15 billion. Because the work of the clinical laboratories is so intricately connected with the care of patients without high quality laboratory services America's health care system is in jeopardy.

While the Clinical Laboratory Improvement Act of 1967 resulted in improved quality of laboratory performance, current law covers only the large interstate laboratories, less than 10 percent of all laboratories throughout the country.

We learned at hearings we held in the 94th and 95th Congress, the American people have had to depend on a variety of other sources to assure the quality and reliability of laboratory work.

This patchwork system of regulation has not adequately served either the doctor or his or her patient. HEW's Forward Plan for Health for fiscal years 1978 through 1982 indicated that "the accuracy and precision of laboratory results continues to be a national problem with error rates ranging from 8 to 25 percent."

The Clinical Laboratory Improvement Act of 1979 is designed to improve the quality of laboratory performance by requiring all laboratories to comply with national standards designed to assure accurate and reliable testing.

This bill allows us to achieve this result without creating a new Federal bureaucracy. The program will be meshed into the already existing Medicare certification program which is staffed and administered by state personnel in every state.

The bill also has cost saving provisions by amending Medicare to discourage unwarranted markups of bills for laboratory services and to place reasonable limitations on payments to hospital based pathologists.

[The texts of S. 544, S. 230, and S. 590 follow:]

96TH CONGRESS  
1ST SESSION

**S. 544**

To amend titles XV and XVI of the Public Health Service Act to revise and extend the authorities and requirements under those titles for health planning and health resources development.

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## IN THE SENATE OF THE UNITED STATES

MARCH 5 (legislative day, FEBRUARY 22), 1979

Mr. KENNEDY (for himself, Mr. SCHWEIKER, Mr. WILLIAMS, Mr. RANDOLPH, Mr. PELL, Mr. CRANSTON, Mr. RIEGLE, and Mr. JAVITS) introduced the following bill; which was read twice and referred to the Committee on Human Resources

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## A BILL

To amend titles XV and XVI of the Public Health Service Act to revise and extend the authorities and requirements under those titles for health planning and health resources development.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3                       SHORT TITLE: REFERENCE TO ACT

4       SECTION 1. (a) This Act may be cited as the "Health  
5       Planning Amendments of 1979".

II—E



1       (b) Whenever in this Act an amendment or repeal is  
2 expressed in terms of an amendment to, or repeal of, a sec-  
3 tion or other provision, the reference shall be considered to  
4 be made to a section or other provision of the Public Health  
5 Service Act.

6 TITLE I—REVISION AND EXTENSION OF NA-  
7 TIONAL HEALTH PLANNING AND DEVELOP-  
8 MENT AUTHORITY

9       SEC. 101. (a) Section 1503(b)(1) is amended by (1) strik-  
10 ing “fifteen” and inserting in lieu thereof “twenty”; (2) in-  
11 serting “the Assistant Secretary for Rural Development of  
12 the Department of Agriculture,” after “Defense,”; and (3)  
13 striking “not less than five shall be persons who are not pro-  
14 viders of health services” and inserting in lieu thereof: “not  
15 less than eight shall be persons who are not providers of  
16 health services including individuals who are members of  
17 urban and rural medical underserved populations”.

18       (b) The last sentence of section 1511(a) is amended by  
19 (1) striking “if the Governor of each State” and inserting in  
20 lieu thereof “if the Governor of any State” and (2) striking  
21 “in order to meet the other requirements of this subsection”.

22       (c) Section 1501(b)(1) is amended by adding at the end  
23 thereof the following “Such standards shall reflect the unique  
24 circumstances and needs of medical underserved populations  
25 including isolated rural communities.”.

1       SEC. 102. Section 1511(b)(4) is amended to read as fol-  
2   lows:

3       “(4)(A) The Secretary shall review on his own initiative  
4   or at the request of any Governor or designated health sys-  
5   tems agency the appropriateness of the boundaries of the  
6   health service areas established under paragraph (3) and, if  
7   he determines that the boundaries for a health service area  
8   no longer meet the requirements of subsection (a), or if the  
9   boundaries for a proposed revised health service area meet  
10   the requirements of subsection (a) in a significantly more ap-  
11   propriate manner in terms of the efficiency and effectiveness  
12   of health planning efforts, he shall revise the boundaries in  
13   accordance with the procedures prescribed by paragraph  
14   (3)(B)(ii). If the Secretary acts on his own initiative to revise  
15   the boundaries of any health service area, he shall consult  
16   with the Governor of the appropriate State or States, the  
17   chief executive officer or agency of the political subdivisions  
18   within the State or States that would be affected by the revi-  
19   sion, the appropriate designated health systems agency or  
20   agencies and the appropriate established Statewide Health  
21   Coordinating Council. A Governor may request a revision of  
22   the boundaries of a health service area only after consultation  
23   with the Governor of any other appropriate State or States,  
24   the chief executive officer or agency of the political subdivi-  
25   sions within the State or States that would be affected by the

1 revision, the appropriate designated health systems agencies,  
2 and the appropriate established Statewide Health Coordinat-  
3 ing Council and shall include in such request the comments  
4 concerning the proposed revision made by such individuals  
5 and entities. A designated health systems agency may make  
6 a request to revise the boundaries of its health service area  
7 only after consultation with the Governor of the appropriate  
8 State or States, the chief executive officer or agency of the  
9 political subdivisions within the State or States that would be  
10 affected by the revision, the other appropriate designated  
11 health system agency or agencies, and the appropriate estab-  
12 lished Statewide Health Coordinating Council and shall in-  
13 clude in such request the comments concerning the proposed  
14 revision made by such individuals and entities. No proposed  
15 revision of the boundaries of a health service area shall com-  
16 prise an entire State without the prior consent of the Gover-  
17 nor of such State. In addition, for each proposed revision of  
18 the boundaries of a health service area, the Secretary shall  
19 give notice and an opportunity for a hearing on the record by  
20 all interested persons and make a written determination of  
21 his findings and decision.

22 “(B) The Secretary shall, by January 1, 1980, by regu-  
23 lation establish criteria for the revision of the boundaries of  
24 health service areas.”.

25 SEC. 103. Section 1511(c) is repealed.

1        SEC. 104. (a) Section 1512(b) is amended by adding the  
2 following new subsection at the end thereof:

3        “(7) CONFLICT OF INTEREST.—Each health systems  
4 agency shall adopt procedures in accordance with regulations  
5 promulgated by the Secretary to insure that no member, em-  
6 ployee, consultant or agent participates in any matter regard-  
7 ing any person, institution, organization or other entity with  
8 which he or she has or has had within the past three years  
9 any substantial direct or indirect employment, fiduciary, com-  
10 petitive, medical staff, or ownership or other financial inter-  
11 est.”.

12        (b) Section 1524(b) is amended by adding at the end  
13 thereof the following new paragraph:

14        “(4) A SHCC shall adopt procedures in accordance with  
15 regulations promulgated by the Secretary to insure that no  
16 member, employee, consultant or agent participates in any  
17 matter regarding any person, institution, organization or  
18 other entity with which he or she has or has had within the  
19 past three years any substantial direct or indirect employ-  
20 ment, fiduciary, competitive, medical staff, or ownership or  
21 other financial interest.”.

22        SEC. 105. (a) The first sentence of section 1512(b)(2)(A)  
23 is amended by—

24                (1) inserting “, to the extent practicable,” after  
25        “shall”,

1           (2) striking "health planning" and inserting in lieu  
2 thereof "health and mental health planning",

3           (3) striking "health resources" and inserting in  
4 lieu thereof "health and mental health resources", and

5           (4) inserting before the period at the end thereof  
6        ", (v) financial and economic analysis, and (vi) public  
7 health and prevention of disease".

8       (b) The second sentence of section 1512(b)(2)(A) is  
9 amended by striking "health resources" and inserting in lieu  
10 thereof "health and mental health resources".

11       (c) Section 1512(b)(2)(A) is amended by adding at the  
12 end the following: "At least one member of the staff shall be  
13 designated to have the responsibility of providing the con-  
14 sumer members of the governing body of an agency with  
15 such assistance as they may require to effectively perform  
16 their functions.".

17       SEC. 106. Section 1512(b)(3) is amended by adding  
18 after subparagraph (C) the following new subparagraph:

19       "(D) SELECTION.—Each health systems agency shall  
20 establish a process for the selection of the members of its  
21 governing body and any subarea advisory councils which  
22 process is designed to assure that (i) such members are se-  
23 lected in accordance with the requirements of subparagraph  
24 (C), (ii) there is the opportunity for broad participation in  
25 such process by the residents of the health service area of the

1 agency, and (iii) the participation of such residents will be  
2 encouraged and facilitated. Such process shall prohibit the  
3 selection of members of such body by members of such body  
4 and members of such councils by members of such council.  
5 Each agency shall make public such process and report it to  
6 the Secretary.”.

7 SEC. 107. (a) Section 1512(b)(3)(A) is amended by in-  
8 serting before the period at the end of the first sentence the  
9 following: “except that a public regional planning body or  
10 unit of general local government which is a health systems  
11 agency is not required to delegate to its governing body for  
12 health planning the exclusive authority to—

13 “(i) appoint and with cause remove members of  
14 the governing body for health planning;

15 “(ii) establish personnel rules and practices for the  
16 staff of the governing body for health planning;

17 “(iii) approve the agency’s budget; or,

18 “(iv) any combination of the activities described in  
19 clauses (i), (ii), and (iii).”

20 (b) Section 1512(b)(3)(C)(iii)(I) is amended by (1) strik-  
21 ing “and other representatives of governmental authorities”  
22 and inserting in lieu thereof “and other representatives of  
23 units of general purpose local government” and (2) adding at  
24 the end thereof the following new sentences: “To be consid-  
25 ered a representative of a unit of general purpose local gov-

1 ernment, an individual must be appointed by such unit or a  
2 combination thereof. For the purpose of this clause, the State  
3 government of a State which is comprised of a single health  
4 service area shall be deemed to be a unit of general purpose  
5 local government.”.

6 SEC. 108. Section 1512(b)(3)(B)(vi) is amended by (1)  
7 striking out “reimburse” and by inserting in lieu thereof “re-  
8 imburse (or when appropriate make advances to)” and (2)  
9 inserting “and performing any other duties and functions of  
10 the health systems agency” after “governing body”.

11 SEC. 109. (a) Section 1512(b)(3)(B)(viii) is amended by  
12 (1) inserting “, except for meetings or portions thereof called  
13 to discuss the performance or remuneration of an individual  
14 employee of the health systems agency which if public would  
15 constitute a clearly unwarranted invasion of the personal pri-  
16 vacy of such employee” after “conduct its business meetings  
17 in public” and (2) inserting “, except for personnel records  
18 and data regarding an individual employee the disclosure of  
19 which would constitute a clearly unwarranted invasion of the  
20 personal privacy of such employee,” after “records and  
21 data”.

22 (b) Section 1512(b)(6)(A) is amended by inserting “,  
23 except to personnel records and data regarding an individual  
24 employee the disclosure of which would constitute a clearly

1 unwarranted invasion of the personal privacy of such employ-  
2 ee" after "such access thereto".

3 (c) Section 1522(b)(6) is amended by (1) inserting "  
4 except for meetings or portions thereof called to discuss the  
5 performance or remuneration of an individual employee of the  
6 State Agency which if public would constitute a clearly un-  
7 warranted invasion of the personal privacy of such employ-  
8 ee" after "conduct its business meetings in public" and (2)  
9 inserting ", except for personnel records and data regarding  
10 an individual employee the disclosure of which would consti-  
11 tute a clearly unwarranted invasion of the personal privacy of  
12 such employee," after "records and data."

13 (d) Section 1532(b)(10) is amended by inserting "  
14 except to personnel records and data regarding an individual  
15 employee the disclosure of which would constitute a clearly  
16 unwarranted invasion of the personal privacy of such employ-  
17 ee," after "State Agency review."

18 SEC. 110. Section 1512(b)(3)(C)(i) is amended by (1)  
19 striking "(nor within the twelve months preceding appoint-  
20 ment been)" and (2) inserting "including but not limited to  
21 unions and corporations" after "major purchasers of health  
22 care".

23 SEC. 111. (a) The first sentence of section  
24 1512(b)(3)(C)(ii) is amended by inserting "or have their prin-  
25 cipal place of business within" after "residents of".



1 (b) Section 1512(b)(3)(C) is amended by striking "health  
2 care" each place it occurs and inserting in lieu thereof  
3 "health or mental health care".

4 (c) Section 1512(b)(3)(C)(ii)(II) is amended by inserting  
5 "rehabilitation facilities," after "long-term care facilities".

6 SEC. 112. (a) The first sentence of section  
7 1512(b)(3)(C)(ii) is amended by inserting "including doctors of  
8 medicine and osteopathy" after "(I) physicians".

9 (b) Section 1531(3)(A) is amended by inserting "(a  
10 doctor of medicine and a doctor of osteopathy)" after "includ-  
11 ing a physician".

12 (c) Section 1531(3) is amended by striking "provider of  
13 health care" each place it occurs and inserting in lieu thereof  
14 "provider of health or mental health care".

15 SEC. 113. The first sentence of section 1512(b)(3)(C)(ii)  
16 is amended by (1) striking "and" after "health professional  
17 schools," and inserting before the period at the end thereof "  
18 (VI) non-professional health workers and (VII) other provid-  
19 ers of health or mental health care" and (2) striking "sub-  
20 stance" and inserting in lieu thereof "alcohol and drug".

21 SEC. 114. (a) Section 1512(b)(3)(C)(iii)(II) is amended  
22 by inserting "at least" before "equal".

23 (b) Section 1512(b)(3)(C)(iii)(III) is amended by inserting  
24 "non-voting" before "ex officio".

1        SEC. 115. Section 1512(b)(3)(C)(iv) is amended by (1)  
2 striking “of its members” and “, to the extent practicable,”  
3 and (2) striking “the representation on such subcommittee or  
4 group described in this subparagraph” and inserting in lieu  
5 thereof “that a majority of the members of any such subcom-  
6 mittee or group are consumers of health or mental health  
7 care”.

8        SEC. 116. (a) Section 1512(b)(4) is amended by (1) strik-  
9 ing “member or employee” and inserting in lieu thereof  
10 “member, employee, consultant or agent” and (2) striking “if  
11 he has acted within the scope of such duty, function, or activ-  
12 ity, has exercised due care, and has acted, with respect to  
13 that performance, without malice toward any person affected  
14 by it” and inserting in lieu thereof “if he could have reason-  
15 ably believed he was acting within the scope of such duty,  
16 function, or activity, and acted, with respect to that perform-  
17 ance, without gross negligence or malice toward any person  
18 affected by it”.

19        (b) Section 1524 is amended by adding at the end there-  
20 of the following new subsection:

21        “(d) No individual who, as a member, employee, consul-  
22 tant or agent of a SHCC shall, by reason of his performance  
23 of any duty, function or activity required of, or authorized to  
24 be undertaken by the SHCC, be liable for payment of dam-  
25 ages under any law of the United States or any State (or

1 political subdivision thereof) if he could have reasonably be-  
2 lieved he was acting within the scope of such duty, function,  
3 or activity, and acted, with respect to that performance,  
4 without gross negligence or malice toward any person affect-  
5 ed by it.”.

6 SEC. 117. Section 1512(b)(6) is amended by redesignat-  
7 ing subparagraphs (A), (B), and (C) as subparagraphs (B),  
8 (C), and (D) and by adding before subparagraph (B) (as so  
9 redesignated) the following:

10 “(A) provide that any executive committee of the  
11 agency and any entity appointed by the governing  
12 body or executive committee of the agency and any  
13 subarea advisory council shall (i) conduct its business  
14 meetings in public (except for meetings or portions  
15 thereof called to discuss the performance or remunera-  
16 tion of an individual employee which if public would  
17 constitute a clearly unwarranted invasion of the per-  
18 sonal privacy of such employee), (ii) give adequate  
19 notice of its meetings to those persons who have re-  
20 quested such notice, and (iii) make its records and data  
21 available, upon request, to the public (other than per-  
22 sonnel records and data regarding an individual em-  
23 ployee the disclosure of which would constitute a clear-  
24 ly unwarranted invasion of the personal privacy of such  
25 employee);”.

1        SEC. 118. (a) The first sentence of section 1513(b)(2) is  
2 amended by striking "and" before "(C)" and inserting after  
3 "health resources and services" the following: "; (D) which  
4 describe the institutional health services (as defined in section  
5 1531(5)) needed to provide for the well-being of persons re-  
6 ceiving care within the health service area including, at a  
7 minimum, the number and type of medical facilities, rehabili-  
8 tation facilities, nursing homes, beds, and equipment needed  
9 to provide acute inpatient, psychiatric inpatient, obstetrical  
10 inpatient, neonatal inpatient, long term care, and treatment  
11 for alcohol and drug abuse; the extent to which existing  
12 medical facilities, rehabilitation facilities, nursing homes, beds  
13 and equipment are in need of modernization or conversion to  
14 new uses; and, the extent to which new medical facilities,  
15 rehabilitation facilities, nursing homes, beds and equipment  
16 need to be constructed or acquired; (E) which describe other  
17 health services (other than institutional health services as de-  
18 fined in section 1531(5)) needed to provide for the well-being  
19 of persons receiving care within the health service area in-  
20 cluding, at a minimum, the number and type of health main-  
21 tenance organizations, outpatient (including primary care)  
22 facilities, rehabilitation facilities, facilities for the treatment of  
23 alcohol abuse and drug abuse, and other medical facilities,  
24 and home health agencies and equipment needed to provide  
25 public health services and outpatient care and the extent to

1 which such facilities and equipment are in need of moderniza-  
2 tion or conversion to new uses and the extent to which new  
3 such health maintenance organizations, facilities, home  
4 health agencies and equipment need to be constructed or ac-  
5 quired.”.

6 (b) The second sentence of section 1523(a)(4)(B) is  
7 amended by inserting “and that are consistent except in  
8 emergency circumstances that pose a threat to public health  
9 with the State health plan required by section 1524(c)” after  
10 “found to be needed”.

11 (c) The first sentence of section 1524(c)(2)(A) is amend-  
12 ed by striking “Prepare” and inserting in lieu thereof “With  
13 the concurrence of the Governor, prepare”.

14 (d) Section 1524(c)(2) is amended by (1) redesignating  
15 subparagraph (B) as subparagraph (C) and (2) by inserting  
16 after subparagraph (A) the following new subparagraph:

17 “(B) In addition to the requirements of subpara-  
18 graph (A), a State health plan shall be coordinated  
19 with the State mental health plan developed pursuant  
20 to the Community Mental Health Centers Act, the  
21 State alcohol abuse plan developed pursuant to the  
22 Comprehensive Alcohol Abuse and Alcoholism Preven-  
23 tion Treatment and Rehabilitation Act, and the State  
24 drug abuse plan developed pursuant to the Drug Abuse  
25 Office and Treatment Act of 1972, and shall describe

1 the resource requirements of manpower, facilities,  
2 equipment, and funds necessary to provide access,  
3 availability and quality services at a reasonable cost to  
4 persons receiving care within the State including, at a  
5 minimum—

6 “(i) the institutional health services (as de-  
7 fined in section 1531(5)) comprising, but not limit-  
8 ed to, the number and type of medical facilities,  
9 rehabilitation facilities, nursing homes, beds, and  
10 equipment needed for acute inpatient, psychiatric  
11 inpatient, obstetrical inpatient, neonatal inpatient,  
12 long term care, and treatment for alcohol abuse  
13 and drug abuse; the extent to which existing  
14 medical facilities, rehabilitation facilities, nursing  
15 homes, beds and equipment are in need of mod-  
16 ernization or conversion to new uses; and, the  
17 extent to which new such medical facilities, reha-  
18 bilitation facilities, nursing homes, beds, and  
19 equipment need to be constructed or acquired, and

20 “(ii) other health services (other than institu-  
21 tional health services as defined in section  
22 1531(5)) comprising, but not limited to, the  
23 number and type of health maintenance organiza-  
24 tions, outpatient (including primary care) facilities,  
25 rehabilitation facilities, facilities for the treatment

1 of alcohol abuse and drug abuse, and other medi-  
2 cal facilities, home health agencies and equipment  
3 needed for public health services and outpatient  
4 care and the extent to which such facilities and  
5 equipment are in need of modernization and con-  
6 version to new uses and the extent to which new  
7 such health maintenance organizations, facilities,  
8 home health agencies and equipment need to be  
9 constructed or acquired.”.

10 (e) Section 1524(c)(2) is amended by adding at the end  
11 thereof the following new subparagraph:

12 “(D) If a State health plan as required by this  
13 subsection is not in effect for the State, the Secretary  
14 may not make any grant to the State health planning  
15 and development agency pursuant to section 1525.”.

16 SEC. 119. (a) The second sentence of section 1513(b)(2)  
17 is amended by inserting “in the process of annually reviewing  
18 an HSP, and before amending an HSP” after “Before estab-  
19 lishing an HSP,”.

20 (b) Section 1513(b)(3) is amended by (1) inserting after  
21 “goals of the HSP” the following: “(as revised pursuant to  
22 section 1524(c)(2)(A))” and (2) adding at the end thereof the  
23 following new sentence: “The AIP shall be established, an-  
24 nually reviewed, and amended in accordance with the proce-  
25 dures set forth in the last two sentences of paragraph (2).”.

1 (c) Section 1513(b)(2) is amended by inserting after the  
2 first sentence thereof the following new sentence: "The HSP  
3 shall include identifiable alcohol abuse, drug abuse, and  
4 mental health components, and shall address specifically the  
5 needs of all medical underserved populations in the health  
6 service area."

7 (d) Section 1513(b)(2)(C) is amended by striking "and  
8 are consistent with".

9 (e) Section 1513(b) is amended by adding at the end  
10 thereof the following new paragraph:

11 (5) The agency shall submit to the State Health  
12 Planning and Development Agency, the Statewide  
13 Health Coordinating Council, and the Secretary a de-  
14 tailed statement of the reasons for any inconsistencies  
15 between its HSP and AIP and the national guidelines  
16 and priorities established under this Act."

17 SEC. 120. Section 1513(c)(2) is amended by (1) striking  
18 "may" and inserting in lieu thereof "shall" and (2) inserting  
19 "in obtaining and filling out the necessary forms and may  
20 provide other technical assistance" after "technical assist-  
21 ance".

22 SEC. 121. (a) The fourth sentence of section 1513(c)(3)  
23 is amended by inserting "except that if such grant or contract  
24 is renewed, funds may be carried forward to the subsequent  
25 grant or contract period without being deducted from the



1 amount of the subsequent grant or contract” before the  
2 period at the end thereof.

3 (b) The second sentence of section 1516(a) is amended  
4 by striking “renewed (as the case may be)” and inserting in  
5 lieu thereof “in the event that the grant is renewed, may be  
6 carried forward to the subsequent grant period without being  
7 deducted from the subsequent grant award”.

8 (c) The second sentence of section 1525(a) is amended  
9 by striking “renewed” and inserting in lieu thereof “in the  
10 event that the grant is renewed, may be carried forward to  
11 the subsequent grant period without being deducted from the  
12 subsequent grant award”.

13 (d) Section 1526(c)(1) is amended by inserting “except  
14 that if such a grant is renewed, funds may be carried forward  
15 to the subsequent grant period without being deducted from  
16 the subsequent grant award” after “such grant was made”.

17 SEC. 122. (a) Section 1513(d) is amended by (1) insert-  
18 ing “(including area agencies on aging, local and regional  
19 alcohol abuse, drug abuse, and mental health planning agen-  
20 cies)” after “administrative agencies” in paragraph (3); (2)  
21 redesignating paragraph “(4)” as paragraph “(5); (3) striking  
22 “and” in paragraph (3); and (4) adding after paragraph (3)  
23 the following new paragraph:

24 “(4) any entity of the State in which the agency  
25 is located which reviews the rates and budgets of

1 health care facilities located in the agency's health  
2 service area, and".

3 (b) Section 1522(b)(7)(A) is amended by inserting "and  
4 for the coordination by the State Agency in the conduct of its  
5 activities with any entity of the State which reviews the rates  
6 and budgets of health care facilities in the State" after  
7 "health care,".

8 SEC. 123. (a) Section 1513(g) is amended by adding at  
9 the end thereof the following new paragraph:

10 "(3) In making the appropriateness review re-  
11 quired by paragraph (1), each health systems agency  
12 shall address at a minimum issues of need, accessibil-  
13 ity, financial viability, cost effectiveness, costs and  
14 charges to the public, and quality of service provided.".

15 (b) Section 1513(e)(1)(B) is amended by (1) striking "in-  
16 tended for use in the health service" and inserting in lieu  
17 thereof "that would make a significant change in the health  
18 services offered within the health service area" and (2) strik-  
19 ing "the delivery of health services" and inserting in lieu  
20 thereof "to support the delivery of health services which  
21 would make a significant change in the health services of-  
22 fered in the health service area".

23 SEC. 124. Section 1513(g)(1) is amended by (1) striking  
24 "all" and inserting in lieu thereof "at least those" and (2)

1 inserting "identified in the State health plan prepared pursu-  
2 ant to section 1524(c)(2)" before "offered".

3 SEC. 125. Section 1514 is amended by striking "may"  
4 and inserting in lieu thereof "shall".

5 SEC. 126. (a) The last sentence of section 1515(b) is  
6 deleted.

7 (b) The last sentence of section 1515(c)(2) is deleted.

8 SEC. 127. (a)(1) Paragraphs (1) and (3) of section  
9 1515(c) are each amended by striking out "twelve months"  
10 and inserting in lieu thereof "thirty-six months".

11 (2) Section 1515(c)(1) is amended—

12 (A) by inserting "(A)" after "(c)(1)",

13 (B) by redesignating subparagraphs (A) and (B) as  
14 clauses (i) and (ii), respectively.

15 (C) by amending clause (ii) (as so redesignated) to  
16 read as follows:

17 "(ii) by the Secretary if the Secretary deter-  
18 mines, in accordance with subparagraph (B), that  
19 the entity is not complying with the provisions of  
20 such agreement.", and

21 (D) by adding at the end the following:

22 "(B) Before the Secretary may terminate, under  
23 subparagraph (A)(ii), an agreement with an entity for  
24 designation as the health systems agency for a health  
25 service area, the Secretary shall—

1                   “(i) consult with the Governor and the  
2                   Statewide Health Coordinating Council of each  
3                   State in which is located the health service area  
4                   respecting the proposed termination,

5                   “(ii) give the entity notice of the intention to  
6                   terminate the agreement and in the notice specify  
7                   with particularity (I) the basis for the determina-  
8                   tion of the Secretary that the entity is not in com-  
9                   pliance with the agreement, and (II) the actions  
10                  that the entity should take to come into compli-  
11                  ance with the agreement, and

12                  “(iii) provide the entity with a reasonable op-  
13                  portunity for a hearing, before an officer or em-  
14                  ployee of the Department of Health, Education,  
15                  and Welfare designated for such purpose, on the  
16                  matter specified in the notice.”.

17                  (3) The amendments made by paragraphs (1) and (2)  
18                  shall take effect with respect to designation agreements en-  
19                  tered into under section 1515(c) of the Public Health Service  
20                  Act after the date of the enactment of this Act.

21                  (b) Section 1515(c) (as amended by subsection (a)) is  
22                  amended by adding after clause (ii) of paragraph (1) (A) the  
23                  following: “A designation agreement under this subsection  
24                  may be terminated by the Secretary before the expiration of  
25                  its term if the health service area with respect to which the

1 agreement was entered into is revised under section  
2 1511(b)(4) and the Secretary determines, after consultation  
3 with the Governor and Statewide Health Coordinating Coun-  
4 cil of each State in which the health service area (as revised)  
5 is located, that the health systems agency designated under  
6 such agreement cannot effectively carry out the agreement  
7 for the area (as revised). In terminating an agreement under  
8 the preceding sentence, the Secretary shall provide that the  
9 termination shall not take effect before an agreement for the  
10 designation of a new agency takes effect and shall provide  
11 the agency designated under the agreement to be terminated  
12 an opportunity to terminate its affairs in a satisfactory  
13 manner.”.

14 (c) Section 1515(c)(3) is amended by (1) inserting “(A)”  
15 after “(3)”; (2) inserting “during the period of the agreement  
16 to be renewed” after “section 1513”; and (3) by adding at  
17 the end thereof the following new paragraphs:

18 “(B) If upon review (as provided in section 1535)  
19 of the agency’s operation and performance of its func-  
20 tions, the Secretary determines that it has not fulfilled,  
21 in a satisfactory manner, the functions of a health sys-  
22 tems agency prescribed by section 1513 during the  
23 period of the agreement to be renewed or does not  
24 continue to meet the requirements of section 1512(b),  
25 he may terminate such agreement or return such

1       agency to a conditionally designated status under sub-  
2       section (b) for a period not to exceed twelve months.  
3       At the end of such period, the Secretary shall either  
4       terminate its agreement with such agency or enter into  
5       an agreement with such agency under paragraph (1).

6               “(C) Before renewing an agreement with a health  
7       systems agency under this subsection, the Secretary  
8       shall provide the State health planning and develop-  
9       ment agency and the Statewide Health Coordinating  
10      Council of the State in which the health systems  
11      agency is located an opportunity to comment on the  
12      performance of such agency and to provide a recom-  
13      mendation on whether such agreement should be re-  
14      newed and whether its renewal should be made subject  
15      to conditions as authorized by paragraph (3).

16              “(D) If the Secretary enters into an agreement  
17      under this subsection with an entity or renews such an  
18      agreement, the Secretary shall notify the Governor of  
19      the State in which such entity is located of the agree-  
20      ment, its renewal, and, if any conditions have been im-  
21      posed under paragraph (3), such conditions.”.

22      (d) The last sentence of section 1515(c)(2) is amended to  
23      read as follows: “In considering such applications, the Secre-  
24      tary shall give priority to any application which has been

1 recommended by a Governor or a Statewide Health Coordi-  
2 nating Council for approval.”.

3 (c) Section 1515(b)(4) is amended by striking out the  
4 last sentence and substituting: “In considering such applica-  
5 tions, the Secretary shall give priority to any application  
6 which has been recommended by a Governor or a Statewide  
7 Health Coordinating Council for approval. When the Secre-  
8 tary enters into an agreement with an entity under paragraph  
9 (1), the Secretary shall notify the Governor of the State in  
10 which such entity is located of such agreement.”.

11 SEC. 128. Section 1515(d) is amended by (1) inserting  
12 “agreement” after “If a designation” and (2) inserting “or is  
13 not renewed” after “prescribed for its expiration”.

14 SEC. 129. (a) Section 1516(b)(2)(A)(i) is amended to  
15 read as follows:

16 “(i) the greater of (I) the amount determined  
17 under paragraph (1) without regard to this paragraph  
18 or paragraph (3), or (II) the amount determined under  
19 paragraph (3), and”.

20 (b) Section 1516(b)(3) is amended to read as follows:

21 “(3) The amount of a grant under subsection (a) to a  
22 health systems agency designated under section 1515(c) may  
23 not be less than \$250,000 in the fiscal year ending Septem-  
24 ber 30, 1980, \$270,000 in the fiscal year ending September  
25 30, 1981, and \$290,000 in any succeeding fiscal year.”.

1 (c) Section 1516(c)(1) is amended by (1) striking "and"  
2 after "1976" and (2) inserting ", \$150,000,000 for the fiscal  
3 year ending September 30, 1980, \$175,000,000 for the fiscal  
4 year ending September 30, 1981, and \$200,000,000 for the  
5 fiscal year ending September 30, 1982" before the period.

6 (d) Section 1516(c) is amended by redesignating para-  
7 graph (2) as paragraph (3) and inserting after paragraph (1)  
8 the following new paragraph:

9 "(2) Of the amount appropriated under paragraph (1) for  
10 any fiscal year, the Secretary may use not more than 5 per  
11 centum of such amount to increase the amount of a grant in  
12 such fiscal year to a health systems agency under subsection  
13 (a) to assist the agency in meeting extraordinary expenses  
14 (including, but not limited to, extraordinary expenses result-  
15 ing from the agency's health systems area being located in  
16 more than one State, from the agency serving a large rural  
17 or urban medical underserved population, or a geographically  
18 large health service area) which would not be covered under  
19 the amount of the grant that would be available to the  
20 agency under this subsection."

21 (e) Section 1516(c)(2) is amended by striking out "  
22 except that" and all that follows in that section and inserting  
23 in lieu thereof a period.

24 SEC. 130. Section 1516(b) is further amended by adding  
25 at the end the following new paragraph:



1       “(4) For the fiscal year ending September 30, 1979, if  
2 the amount of the grant of a health systems agency is deter-  
3 mined under paragraph (b)(3) of this section, and if the appli-  
4 cation of such grant contains assurances satisfactory to the  
5 Secretary that the agency will expend or obligate in the  
6 period in which such grant will be available for obligation  
7 non-Federal funds meeting the requirements of subparagraph  
8 (B) for the purposes for which such grant may be made such  
9 grant shall be increased by an amount equal to the lesser of  
10 (I) the amount of such non-Federal funds with respect to  
11 which the assurances were made, or (II) the product of \$0.25  
12 and the population of the health service area for which the  
13 agency is designated.”.

14       SEC. 131. (a) Section 1521(b)(4) is amended by (1) in-  
15 serting “(A)” after “(4)”; (2) inserting “upon review (as pro-  
16 vided in section 1535) of the State Agency’s operation and  
17 performance of its function.” before “he determines”; (3)  
18 adding at the end of paragraph (4)(A) (as so redesignated) the  
19 following: “Before renewing an agreement under this para-  
20 graph within a State Agency for a State, the Secretary shall  
21 provide each health systems agency designated for a health  
22 service area located (in whole or in part) in such State and  
23 the Statewide Health Coordinating Council an opportunity to  
24 comment on the performance of the State Agency and to  
25 provide a recommendation on whether such agreement

1 should be renewed.”; and (4) adding at the end thereof the  
2 following new paragraph: “(B) If upon review (as provided in  
3 section 1535) of the State Agency’s operation and perform-  
4 ance of its functions, the Secretary determines that it has not  
5 fulfilled, in a satisfactory manner, the responsibilities of a  
6 State Agency during the period of the agreement to be re-  
7 newed or if the applicable State administrative program does  
8 not continue to meet the requirements of section 1522, he  
9 may terminate such agreement or return the State Agency to  
10 a conditionally designated status under paragraph (2) of sub-  
11 section (b) for a period not to exceed twelve months. At the  
12 end of such period, the Secretary shall either terminate its  
13 agreement with such State Agency or enter into an agree-  
14 ment with such State Agency under paragraph (3) of subsec-  
15 tion “(b).”.

16 (b)(1) Paragraphs (3) and (4) of section 1521(b) are each  
17 amended by striking out “twelve months” and inserting in  
18 lieu thereof “thirty-six months”.

19 (2) Section 1521(b)(3) is amended—

20 (A) by inserting “(A)” after “(3)”,

21 (B) by redesignating subparagraphs (A) and (B) as  
22 clauses (i) and (ii), respectively,

23 (C) by amending clause (ii) (as so redesignated) to  
24 read as follows:

1           “(ii) by the Secretary if the Secretary deter-  
2           mines, in accordance with subparagraph (B), that  
3           the designated State Agency is not complying  
4           with the provisions of such agreement.”, and  
5           (D) by adding at the end the following:

6           “(B) Before the Secretary may terminate an  
7           agreement with a designated State Agency under sub-  
8           paragraph (A)(ii), the Secretary shall—

9           “(i) consult with the Statewide Health Co-  
10          ordinating Council of the State for which the  
11          State Agency is designated respecting the pro-  
12          posed termination,

13          “(ii) give the State Agency notice of the in-  
14          tention to terminate the agreement and in the  
15          notice specify with particularity (I) the basis for  
16          the determination of the Secretary that the State  
17          Agency is not in compliance with the agreement,  
18          and (II) the actions that the State Agency should  
19          take to come into compliance with the agreement,  
20          and

21          “(iii) provide the State Agency with a rea-  
22          sonable opportunity for a hearing, before an offi-  
23          cer or employee of the Department of Health,  
24          Education, and Welfare designated for such pur-  
25          pose, on the matter specified in the notice.”.

1       (3) The amendments made by paragraphs (1) and (2)  
2 shall apply with respect to designation agreements entered  
3 into under section 1521(b)(3) of the Public Health Service  
4 Act after the date of the enactment of this Act.”.

5       SEC. 132. Section 1521(d) is amended to read as fol-  
6 lows: “If an agreement under this section for the designation  
7 of a State Agency for a State is not in effect by September  
8 30, 1980, the Secretary shall reduce by 25 per centum the  
9 amount of any allotment, grant, loan, loan guarantee to be  
10 made and the amount, if any, of any contract to be entered  
11 into under this Act, the Community Mental Health Centers  
12 Act, or the Comprehensive Alcohol Abuse and Alcoholism  
13 Prevention, Treatment, and Rehabilitation Act of 1970 for  
14 the development, expansion, or support of health resources in  
15 such State until such time as such an agreement is in effect.  
16 If such an agreement is not in effect by September 30, 1981,  
17 the Secretary shall reduce such amounts by 50 per centum  
18 until such time as such an agreement is in effect. If such an  
19 agreement is not in effect by September 30, 1982, the Secre-  
20 tary shall reduce such amounts by 75 per centum until such  
21 time as such an agreement is in effect. If such an agreement  
22 is not in effect by September 30, 1983, the Secretary shall  
23 reduce such amounts by 100 per centum until such time as  
24 such an agreement is in effect.”.

1        SEC. 133. (a) Section 1522(b) is amended by adding at  
2 the end thereof the following paragraph:

3            “(14) Provides that any person who is adversely  
4 affected by a final decision of the State Agency pursu-  
5 ant to paragraph (4), (5), or (6) of section 1523(a) may,  
6 within a reasonable period of time after such a decision  
7 is made and any review is made pursuant to paragraph  
8 (13), obtain judicial review of such a decision in an ap-  
9 propriate State court. Upon such judicial review, the  
10 decision of the State Agency shall be affirmed unless it  
11 is arbitrary or capricious, or was made not in conform-  
12 ity with the applicable law.”.

13        (b) Section 1522(b)(13)(A) is amended by inserting “in a  
14 timely manner” after “reviewed”.

15        SEC. 134. Section 1522(c) is amended by striking “once  
16 each year” and inserting in lieu thereof “once every three  
17 years”.

18        SEC. 135. (a) Section 1523(a) is amended by adding the  
19 following new paragraph at the end thereof:

20            “(7) Provide technical assistance in obtaining and  
21 filling out the necessary forms to individuals and public  
22 and private entities for the development of projects and  
23 programs.”.

24        (b) Section 1523(a)(2) is amended to read as follows:

1           “(2) Prepare and review and revise as necessary  
2        (but at least annually) a preliminary State health plan  
3        which shall be made up of the HSP's of the health sys-  
4        tems agencies within the State. The State Agency  
5        shall refer the alcohol abuse, drug abuse, and mental  
6        health components of such HSP's to the State alcohol-  
7        ism, drug abuse, and mental health authorities, respec-  
8        tively, designated by the Governor, to review their re-  
9        spective components and to prepare the alcohol abuse,  
10       drug abuse, and the mental health components of the  
11       preliminary State health plan. The alcohol abuse, drug  
12       abuse, and mental health components of such prelimi-  
13       nary plan may, as found necessary by such State au-  
14       thorities, contain such revisions of the alcohol abuse,  
15       drug abuse, and mental health components of such  
16       HSP's to achieve their appropriate coordination or to  
17       deal more effectively with statewide alcohol abuse,  
18       drug abuse, and mental health needs. The remainder of  
19       such preliminary plan may, as found necessary by the  
20       State Agency, contain such revisions of such HSP's to  
21       achieve their appropriate coordination or to deal more  
22       effectively with statewide needs. The preliminary State  
23       health plan shall be submitted to the Statewide Health  
24       Coordinating Council of the State for approval or dis-

1 approval and for use in developing the State health  
2 plan referred to in section 1524(c)."

3 SEC. 136. (a) Section 1523(a)(4) is amended by (1) strik-  
4 ing "which is satisfactory to the Secretary" and inserting in  
5 lieu thereof "which is consistent with standards established  
6 by the Secretary by regulation"; (2) striking "services, facili-  
7 ties, and organizations" each place it occurs and inserting in  
8 lieu thereof "services and facilities"; and (3) inserting before  
9 the last sentence thereof the following: "In addition, such  
10 program shall provide (i) for procedures and penalties to en-  
11 force the provisions of the program and (ii) that after a certifi-  
12 cate of need is issued a periodic review (at least every  
13 twenty-four months) shall be conducted of the progress being  
14 made in making the service or facility for which the certifi-  
15 cate was issued available for use, and if it is determined, after  
16 notice and an opportunity for a hearing on the record, that  
17 substantial progress (absent unforeseen and unavoidable cir-  
18 cumstances) is not being made, the certificate shall be with-  
19 drawn. In addition, each certificate of need in the State that  
20 is issued must be based solely on the record established in  
21 administrative and judicial proceedings (as provided for in  
22 this title) held with respect to an application for such certifi-  
23 cate in order for such certificate of need program to be in  
24 compliance with this paragraph. Notwithstanding any other  
25 section of this title, no such program shall have provisions for

1 the review and determination of need of the services, facili-  
2 ties, equipment, and organization of health maintenance or-  
3 ganizations and the entities through which their services are  
4 provided except for new institutional health services of hospi-  
5 tals controlled directly or indirectly by health maintenance  
6 organizations and diagnostic or therapeutic equipment (as  
7 that term is used in section 1531(5)) of health maintenance  
8 organizations.”.

9 (b) Section 1523 is amended by adding at the end there-  
10 of the following new subsection:

11 “(d)(1) A State certificate of need program shall provide  
12 for review and determination of need prior to the acquisition  
13 of diagnostic or therapeutic equipment (as that term is used  
14 in section 1531(5)) which will not be owned by or located in  
15 a health care facility if—

16 “(A) the notice required by paragraph (2) is not  
17 filed in accordance with that paragraph with respect to  
18 such acquisition, or

19 “(B) the State Agency finds, within thirty days  
20 after the date it receives a notice in accordance with  
21 paragraph (2) with respect to such acquisition, that the  
22 equipment will be used to provide services on a regular  
23 basis for inpatients of a hospital.

24 “(2) Before any person enters into a contractual ar-  
25 rangement to acquire such diagnostic or therapeutic equip-



1 ment which will not be owned by or located in a health care  
2 facility, such person shall notify the State agency of the State  
3 in which such equipment will be located of such person's  
4 intent to acquire such equipment. Such notice shall be made  
5 in writing and shall be made at least thirty days before con-  
6 tractual arrangements are entered into to acquire the equip-  
7 ment with respect to which the notice is given."

8       SEC. 137. Section 1523(a)(5) is amended by inserting  
9 "except that this function shall not be performed if the State  
10 has in effect a certificate of need program as required by  
11 paragraph (4)" after "such services".

12       SEC. 138. (a) Section 1524(c)(1) is amended by striking  
13 "Review annually" and inserting in lieu thereof "Establish  
14 (in consultation with the health systems agencies within the  
15 State and the State agency) a uniform format for HSP's and  
16 AIP's and review annually".

17       (b) The first sentence of section 1513(b)(2) is amended  
18 by inserting "(in accordance with the format prescribed pur-  
19 suant to section 1524(c)(1))" after "established".

20       (c) Section 1524(b)(1) is amended by (1) striking "con-  
21 sumers of health care" each place it occurs and inserting in  
22 lieu thereof "consumers of health care or mental health  
23 care"; (2) striking "providers of health care" each place it  
24 occurs and inserting in lieu thereof "providers of health or

1 mental health care"; and striking "two" in paragraph (D)  
2 and inserting in lieu thereof "one".

3 (d) Section 1524(c)(6) is amended by inserting after  
4 "Community Mental Health Centers Act," the following:  
5 "Sections 409 and 410 of the Drug Abuse Office and Treat-  
6 ment Act,".

7 (e) Section 1524(b)(1) is amended by adding at the end  
8 thereof the following paragraph:

9 " (E) Members of the SHCC who are consumers  
10 of health or mental health care and who are not pro-  
11 viders of health or mental health care must include in-  
12 dividuals who are members of rural and urban medical  
13 underserved populations, if such populations exist in  
14 the State.".

15 SEC. 139. Section 1525(c) is amended by (1) striking  
16 "and" after "1976" and (2) inserting " , \$40,000,000 for the  
17 fiscal year ending September 30, 1980, \$45,000,000 for the  
18 fiscal year ending September 30, 1981, and \$50,000,000 for  
19 the fiscal year ending September 30, 1982" before the  
20 period.

21 SEC. 140. Section 1526(e) is amended by (1) striking  
22 "and" after "1976," and (2) inserting " , \$6,000,000 for the  
23 fiscal year ending September 30, 1980, \$7,000,000 for the  
24 fiscal year ending September 30, 1981, and \$7,000,000 for

1 the fiscal year ending September 30, 1982" before the  
2 period.

3 SEC. 141. (a) Section 1531(3)(A) is amended by (1)  
4 striking "substance" and inserting in lieu thereof "alcohol  
5 and drug" and (2) inserting "rehabilitation facilities," after  
6 "outpatient facilities".

7 (b) Section 1531(3)(B)(i) is amended by inserting  
8 "except that an individual shall not be considered an indirect  
9 provider of health care solely because he is a member of a  
10 governing board of an entity described in subclause (II) or  
11 (IV) of clause (ii)" after "clause (ii)".

12 SEC. 142. Section 1531(5) is amended to read as fol-  
13 lows:

14 "(5)(A) The term 'institutional health services' means (i)  
15 the health services provided through health care facilities as  
16 defined in regulations of the Secretary including, but not lim-  
17 ited to, private and public hospitals, rehabilitation facilities,  
18 and nursing homes if such services entail annual operating  
19 costs of \$50,000 or more; and (ii) diagnostic or therapeutic  
20 equipment, acquired through purchase, rental, lease, or gift,  
21 valued at the time of acquisition in excess of \$150,000 used  
22 in the delivery of health care services by a health care  
23 facility.

24 "(B) In determining whether diagnostic or therapeutic  
25 equipment has a value in excess of \$150,000 for purposes of

1 subparagraph (A), the value of studies, surveys, designs,  
2 plans, working drawings, specifications, and other activities  
3 essential to the acquisition of such equipment shall be includ-  
4 ed.”.

5       SEC. 143. Section 1532(a) is amended by (1) striking  
6 “(e), (f), and (g)” and inserting in lieu thereof “(e), (f), (g), and  
7 (h)” and (2) by adding at the end thereof the following: “Pro-  
8 cedures and criteria for reviews by health systems agencies  
9 pursuant to section 1513(f) and reviews by State Agencies  
10 pursuant to paragraphs (4) and (5) of section 1523(a) must  
11 provide that applications be submitted in accordance with  
12 timetables established by such agencies and Agencies; that  
13 such reviews be undertaken in a timely fashion; and that  
14 completed applications pertaining to similar types of services  
15 or facilities affecting the same service area are considered in  
16 relation to each other at appropriate times (but no less often  
17 than twice a year). Procedures and criteria for reviews by  
18 health systems agencies pursuant to section 1513(g) and by  
19 State Agencies pursuant to section 1523(a)(6) must provide  
20 that reviews of similar types of institutional health services  
21 affecting the same service area be considered in relation to  
22 each other. Health systems agencies and State Agencies  
23 within a State shall cooperate in the development of proce-  
24 dures and criteria under this subsection to the extent appro-

1 piate to the achievement of efficiency in their reviews and  
2 consistency in criteria for such reviews.”.

3 SEC. 144. (a) Section 1532(b)(2) is amended by adding  
4 at the end the following new sentence: “Failure of a health  
5 systems agency or State Agency to complete a review within  
6 the period prescribed for the review may not be deemed by  
7 such an entity to constitute a negative finding, recommenda-  
8 tion, or decision with respect to the subject of such review.”.

9 (b) Section 1524(c) is amended by adding at the end  
10 thereof the following new paragraph:

11 “(7) Failure of a SHCC to complete a review within the  
12 period prescribed for the review may not be deemed by such  
13 an entity to constitute a negative finding, recommendation,  
14 or decision with respect to the subject of such review.”.

15 (c) Section 1532(b) is amended by adding the following  
16 paragraph at the end thereof:

17 “(13) In the case of reviews pursuant to subsections (f)  
18 and (g) of section 1513 and subsections (4), (5), and (6) of  
19 section 1523, and where appropriate for other reviews—

20 “(A) opportunity for each participant to present  
21 evidence and arguments orally and/or by written sub-  
22 mission,

23 “(B) opportunity for each participant to cross ex-  
24 amine any other participant who makes a factual alle-  
25 gation relevant to such a review,

1           “(C) maintenance of a record of the hearing,

2           “(D) provision that the decision of the agency and  
3       Agency be based solely on the record of the hearing,  
4       and

5           “(E) prohibition on ex parte contacts with individ-  
6       uals voting on the review process.”.

7       SEC. 145. Section 1532(b)(1) is amended by (1) striking  
8       “Written” and inserting in lieu thereof “Timely written” and  
9       (2) inserting “and to all other persons who have asked to  
10      have their names placed on a mailing list maintained by the  
11      agency and Agency” after “affected persons”.

12      SEC. 146. Section 1532(b)(7) is amended by striking  
13      “Notification” and inserting in lieu thereof “Timely notifica-  
14      tion”.

15      SEC. 147. Section 1532(b)(8) is amended by inserting  
16      “prior to any decision” after “State Agency review”.

17      SEC. 148. (a) Section 1532(c)(9)(B) is amended by in-  
18      serting “and on the costs and charges to the public of provid-  
19      ing health services by other persons” after “construction  
20      project”.

21      (b) Section 1532(c) is amended by adding after para-  
22      graph (9) the following new paragraphs:

23      “(10) In the case of existing services or facilities, the  
24      quality of care provided by such services or facilities in the  
25      past.

1       “(11) The extent to which such proposed services will  
2 be accessible to all the residents of the area to be served by  
3 such services.”.

4       (c) Section 1532 is amended by adding at the end there-  
5 of the following new subsection:

6       “(d) Notwithstanding subsection (c), an application by a  
7 health maintenance organization (as defined in section  
8 1531(6)(B)) or by a hospital controlled directly or indirectly  
9 by such a health maintenance organization for a certificate of  
10 need for new institutional health services shall be approved  
11 by the State agency if the State agency finds (in accordance  
12 with criteria prescribed by the Secretary) that—

13       “(1) approval of such application is required to  
14 meet the needs of the members of the health mainte-  
15 nance organization and of the new members which  
16 such organization can reasonably be expected to enroll,  
17 and

18       “(2) the health maintenance organization is unable  
19 to provide, through services or facilities which can rea-  
20 sonably be expected to be available to the organization,  
21 its institutional health services in a reasonable and  
22 cost-effective manner which is consistent with the basic  
23 method of operation of the organization and which  
24 makes such services available on a long-term basis

1 through physicians and other health professionals asso-  
2 ciated with it.”.

3 SEC. 149. (a) Section 1534(a) is amended by striking  
4 “or contracts, or both.”.

5 (b) Section 1534(b)(1) is amended by (1) striking “or  
6 contract” each place it occurs; (2) inserting “and be able to  
7 provide assistance and dissemination of information to health  
8 systems agencies and State Agencies as provided in subsec-  
9 tions (a) and (c)” after “paragraph (2)” and (3) inserting “and  
10 is able to provide such assistance and dissemination of infor-  
11 mation” after “such requirements”.

12 (c) Section 1534(c)(2) is amended to read as follows:

13 “(2) shall develop and use methods (satisfactory to  
14 the Secretary) to disseminate to such agencies and  
15 State Agencies planning approaches, methodologies (in-  
16 cluding methodologies to provide for education of new  
17 board members and new staff and continuing education  
18 of board members and staff of such agencies and State  
19 Agencies), policies, and standards.”.

20 (d) Section 1534(d) is amended by (1) striking “and con-  
21 tracts”, (2) striking “and” after “1976,”, and (3) inserting “,  
22 \$12,000,000 for the fiscal year ending September 30, 1980,  
23 \$15,000,000 for the fiscal year ending September 30, 1981,  
24 and \$18,000,000 for the fiscal year ending September 30,  
25 1982,” before the period.



1        SEC. 150. Section 1535 is amended by adding the fol-  
2        lowing new subsection at the end thereof:

3        “(c) In making the reviews required by subsections (c)  
4        and (d), the secretary shall consider the comments submitted  
5        by any interested person.”.

6        SEC. 151. (a) Section 2(a)(3)(B) of Public Law 93-641  
7        is amended by deleting “and” and inserting after section  
8        2(a)(3)(C) the following:

9        “(D) Lack of effective coordination between the  
10        mental health care system and physical health care  
11        system, both by providers and planners, have promoted  
12        fragmentation, lack of continuity, and inappropriate uti-  
13        lization of the Nation’s health care resources: and

14        “(E) lack of attention to and emphasis on the be-  
15        havioral aspects of physical health care and status.”.

16        (b) Section 1502 is amended by adding the following  
17        new subsections at the end thereof:

18        “(11) The promotion of those health services  
19        which are provided in a manner cognizant of the emo-  
20        tional and psychological components of the prevention  
21        and treatment of illness and the maintenance of health.

22        “(12) The elimination of inappropriate placement  
23        in institutions of persons with mental health problems  
24        and improvements in the quality of care provided to

1 persons with mental health problems for whom institu-  
2 tional care is appropriate.

3 “(13) The assurance of access to community  
4 mental health centers and other mental health care  
5 providers for needed mental health services and the  
6 emphasis on outpatient care as a less restrictive alter-  
7 native to inpatient mental health services.”.

8 SEC. 152. Section 1513(e) is amended by—

9 (a) inserting “(as defined in section 4(b) of the  
10 Indian Self-Determination and Education Assistance  
11 Act)” after “Indian tribe” in paragraph (1)(B).

12 (b) redesignating paragraphs (2) and (3) as para-  
13 graphs (3) and (4) respectively and adding after para-  
14 graph (1) the following new paragraph:

15 “(2) When a health systems agency is requested by or  
16 on behalf of a Federal department or agency to review a  
17 proposed use of Federal funds, other than those specified in  
18 subparagraph (A), to support the development of institutional  
19 health services intended for use in the health service area,  
20 the health systems agency shall, within sixty days of receiv-  
21 ing such a request, submit its views on such proposed use to  
22 the Federal department or agency involved and to the appro-  
23 priate Committees of the Congress.”, and

24 (c) adding after paragraph (4) as so redesignated  
25 by subsection (b) the following new paragraph:

1       “(5) Health systems agencies that have an Indian tribe  
2 or intertribal Indian organization (referred to in paragraph  
3 (1)(B)) located within such agencies’ health service areas  
4 shall carry out their functions under this section in a manner  
5 that recognizes tribal self-determination. Such agencies shall  
6 seeks to enter into agreements with the Indian tribes and/or  
7 intertribal organizations located within their health service  
8 areas on matters of mutual concern as defined in regulations  
9 of the Secretary.”.

10       SEC. 153. Section 1531 is amended by adding at the  
11 end thereof the following new paragraphs:

12       “(6)(A) Except as provided in paragraph (B), the term  
13 ‘health maintenance organization’ means a public or private  
14 organization, organized under the laws of any State, which  
15 has had approved an application for assistance under section  
16 1304 or which (1) provides or otherwise makes available to  
17 enrolled participants health care services, including at least  
18 the following basic health care services; usual physician serv-  
19 ices, hospitalization, laboratory, X-ray, emergency and pre-  
20 ventive services, and out of area coverage; (2) is compensat-  
21 ed (except for copayments) for the provision of the basic  
22 health care services listed in paragraph (1) to enrolled partici-  
23 pants on a predetermined periodic rate basis; and (3) provides  
24 physicians’ services primarily (i) directly through physicians  
25 who are either employees or partners of such organization, or

1 (ii) through arrangements with individual physicians or one or  
2 more groups of physicians (organized on a group practice or  
3 individual practice basis).

4 “(B) For the purposes of section 1532(d), the term  
5 ‘health maintenance organization’ means an entity which has  
6 been determined by the Secretary to be a qualified health  
7 maintenance organization pursuant to section 1310(d).

8 “(7) The term ‘medical underserved population’ has the  
9 same meaning as such term has under section 330(b)(3).

10 “(8) The term ‘rehabilitation facility’ means a facility  
11 which is operated for the primary purpose of providing reha-  
12 bilitation services to handicapped individuals, and which pro-  
13 vides singly or in combination one or more of the following  
14 services for handicapped individuals: (A) rehabilitation serv-  
15 ices which shall include, under one management, medical,  
16 psychological, social and vocational services, (B) testing, fit-  
17 ting, or training in the use of prosthetic and orthotic devices,  
18 (C) prevocational conditioning or recreational therapy, (D)  
19 physical and occupational therapy, (E) speech and hearing  
20 therapy, (F) psychological and social services, (G) evaluation  
21 of rehabilitation potential, (H) personal and work adjustment,  
22 (I) vocational training with a view toward career advance-  
23 ment (in combination with other rehabilitation services), (J)  
24 evaluation or control of specific disabilities, (K) orientation  
25 and mobility services to the blind, and (L) extended employ-

1 ment for those handicapped individuals who cannot be readily  
2 absorbed in the competitive labor market, except that all  
3 medical and related health services must be described by, or  
4 under the formal supervision of, persons licensed to prescribe  
5 or supervise the provision of such services in the State.”.

6 SEC. 154. Section 1513(b)(2)(A) is amended by inserting  
7 “(primarily with regard to health care equipment, and health  
8 services provided by health care institutions, health care  
9 facilities, and other providers of health care and other health  
10 resources)” after “healthful environment”.

11 SEC. 155. (a) Except as provided in subsection (b), the  
12 amendments made by this title shall take effect on the date of  
13 the enactment of this Act.

14 (b) The amendments made by sections 104, 105(a),  
15 105(b), 106, 107, 113, 114(a), 118, 119(c), 134(b), 135,  
16 137(a), 137(b), 137(e), and 148(a) shall take effect one year  
17 after the date of enactment of this Act and the amendments  
18 made by sections 143 and 148 shall take effect six months  
19 after the date of enactment of this Act, except that on or  
20 after the date of the enactment of this Act health systems  
21 agencies, State health planning and development agencies,  
22 and Statewide Health Coordinating Councils may make the  
23 organizational and related changes required and may act in  
24 accordance with the changes in their functions made by such  
25 amendments.

1 TITLE II—REVISION AND EXTENSION OF  
2 HEALTH RESOURCES DEVELOPMENT AU-  
3 THORITY

4 SEC. 201. Section 1603(a)(3) is amended by inserting  
5 “and the Governor of the State” after “Council”.

6 SEC. 202. Section 1613 is amended by adding at the  
7 end thereof the following new sentence: “The Secretary may  
8 make funds appropriated for use in fiscal year 1976 under  
9 this section but not expended available to carry out the pur-  
10 poses of section 1625(d) through September 30, 1980.”.

11 SEC. 203. Section 1622(e)(2) is amended by (1) striking  
12 “and” after “1976,” and (2) inserting “, September 30,  
13 1980, September 30, 1981, and September 30, 1982” before  
14 the period.

15 SEC. 204. Section 1625(d) is amended by (1) striking  
16 “the fiscal year ending September 30, 1978” and inserting in  
17 lieu thereof “the fiscal years ending September 30, 1978,  
18 September 30, 1979, September 30, 1980, September 30,  
19 1981, and September 30, 1982” and (2) striking “for such  
20 fiscal year” and inserting in lieu thereof “, \$75,000,000,  
21 \$100,000,000, \$125,000,000, and \$125,000,000 for such  
22 fiscal years respectively”.

23 SEC. 205. Section 1640(d) is amended by (1) striking  
24 “and” after “1976,” and (2) inserting “\$40,000,000 for the  
25 fiscal year ending September 30, 1980, \$70,000,000 for the

1 fiscal year ending September 30, 1981, and \$130,000,000  
2 for the fiscal year ending September 30, 1982" before the  
3 period.

4 SEC. 206. Title XVI is amended by adding at the end  
5 thereof the following new part:

6 "PART G—PROGRAM TO ASSIST AND ENCOURAGE THE  
7 VOLUNTARY DISCONTINUANCE OF UNNEEDED HOS-  
8 PITAL SERVICES

9 "ESTABLISHMENT OF PROGRAM

10 "SEC. 1641. The Secretary shall, by April 1, 1980, es-  
11 tablish a program under which financial assistance and en-  
12 couragement shall be provided, in accordance with this part,  
13 for the consolidation of duplicative hospital services and the  
14 discontinuance of unneeded hospital services.

15 "ASSISTANCE UNDER THE PROGRAM

16 "SEC. 1642. (a)(1) Under the program established under  
17 section 1641, any hospital which was in operation on the  
18 date of enactment of this part and—

19 "(A) which intends to discontinue providing inpa-  
20 tient health services may apply for a debt payment and  
21 an incentive payment under section 1643 for such dis-  
22 continuance,

23 "(B) which intends to discontinue an identifiable  
24 unit of the hospital which provides inpatient health

1 services may apply for an incentive payment under  
2 section 1643 for such discontinuance, or

3 “(C) which intends to convert an identifiable part  
4 of the hospital into providing ambulatory care services,  
5 long term care services, or any other service designat-  
6 ed by the Secretary may apply for a conversion pay-  
7 ment under section 1643 if the State health planning  
8 and development agency which would have jurisdiction  
9 over such service has determined, after taking into  
10 consideration the recommendations of the health sys-  
11 tems agency which would have jurisdiction over such  
12 service, that such service is needed.

13 “(2) The incentive payment authorized by paragraph  
14 (a)(1) may be used for—

15 “(A) the planning, development (including the cost  
16 of construction and the acquisition of equipment), and  
17 delivery of ambulatory care services, home health care  
18 services, long term care services, or other services  
19 (designated by the Secretary) for the community served  
20 by the applicant for such payment, which services the  
21 State health planning and development agency, after  
22 consideration of the recommendations of the health sys-  
23 tems agency with jurisdiction over such community,  
24 has determined are needed;



1           “(B) if the applicant has merged with another  
2   hospital, preparation of that hospital to serve patients  
3   of the closed hospital;

4           “(C) reasonable (as determined under guidelines  
5   prescribed by the Secretary) termination pay for per-  
6   sonnel of the applicant who will lose employment be-  
7   cause of the discontinuance of inpatient services to be  
8   made by the applicant, retraining of such personnel,  
9   and assisting such personnel in securing employment;  
10   or

11           “(D) any combination of the activities described in  
12   subparagraphs (A), (B), and (C).

13           “(b) An application of a hospital for a payment under  
14   section 1643 shall include—

15           “(1) a description of the service (or services) to be  
16   discontinued or the part of the hospital to be convert-  
17   ed;

18           “(2) an evaluation of the impact of such discon-  
19   tinuance or conversion on the provision of health care  
20   in the health service area in which such hospital is lo-  
21   cated;

22           “(3) if the services of a unit of a hospital or of all  
23   services of a hospital are to be discontinued or convert-  
24   ed, an estimate of the change in the applicant's rev-

1 enues which will result from such discontinuance or  
2 conversion;

3 “(4) with respect to the incentive payment for the  
4 discontinuance of all the services of hospital—

5 “(A) a description of the activities for which  
6 the applicant intends to expend such payment,

7 “(B) a description of the means with which  
8 (including a description of any Federal financial  
9 assistance the applicant intends to apply for), and  
10 the manner in which, the applicant will carry out  
11 such activities,

12 “(C) the amount the applicant intends to  
13 expend for such activities, and

14 “(D) if the applicant will not be responsible  
15 for making expenditures for such activities, identi-  
16 fication of the person (or persons) who will be re-  
17 sponsible for making such expenditures;

18 “(5) with respect to the incentive payment for the  
19 discontinuance of an identifiable unit of a hospital, a  
20 description of the use the applicant will make of such  
21 payment;

22 “(6) an evaluation of the impact of such discon-  
23 tinuance or conversion on the employees of such hospi-  
24 tal; and

1           “(7) such other information as the Secretary may  
2       by regulation require.

3 A hospital which has an application under this subsection  
4 approved by the Secretary is entitled to receive the payments  
5 applied for.

6           “(c) The health systems agency for the health service  
7 area in which an applicant under this section is located shall  
8 determine the need for the service (or services) proposed to  
9 be discontinued by such applicant or for the part of the hospi-  
10 tal to be converted, as the case may be, and shall make a  
11 recommendation to the State health planning and develop-  
12 ment agency for the State in which the applicant is located  
13 respecting approval by the Secretary of such applicant’s ap-  
14 plication. A determination of a health systems agency under  
15 this subsection shall be based upon criteria developed pursu-  
16 ant to section 1532(c).

17           “(d) A State health planning and development agency  
18 which has received a recommendation from a health systems  
19 agency under subsection (c) shall, after consideration of such  
20 recommendation, make a recommendation to the Secretary  
21 respecting the approval by the Secretary of the application  
22 with respect to which the health systems agency’s recom-  
23 mendation was made. A State health planning and develop-  
24 ment agency’s recommendation under this subsection with  
25 respect to the approval of an application (1) shall be based

1 upon (A) the need for the service (or services) proposed to be  
2 discontinued by the applicant or for the part of the hospital to  
3 be converted, as the case may be, and (B) such other criteria  
4 as the Secretary may by regulation prescribe, and (2) shall be  
5 accompanied by the health systems agency's recommendation  
6 made with respect to the approval of such application.

7       “(e) In considering applications submitted under this  
8 section, the Secretary shall consider the recommendations of  
9 the State health planning and development agency and the  
10 health systems agency. The Secretary may not approve an  
11 application which a State agency recommends not be ap-  
12 proved.

13       “(f) In determining the need for the service (or services)  
14 proposed to be discontinued by an applicant for payment  
15 under section 1643, a health systems agency and a State  
16 agency shall give special consideration to the unmet needs  
17 and existing access patterns of urban or rural poverty popula-  
18 tions.

19       “(g) For purposes of this title, the term “hospital”  
20 means with respect to any fiscal year, an institution (includ-  
21 ing a distinct part of an institution participating in the pro-  
22 gram established under title XVIII of the Social Security  
23 Act) which satisfies paragraphs (1) and (7) of section 1861(e)  
24 of such Act, but such term does not include a Federal hospi-  
25 tal.

## 1 "AMOUNT OF PAYMENTS

2 "SEC. 1643. (a) The amount of a debt payment which  
3 shall be made to a hospital, with an approved application  
4 under section 1642 for the discontinuance of all of its inpa-  
5 tient services is the sum of—

6 "(1)(A) the lesser of—

7 "(i) the total outstanding financial obligation  
8 of the applicant attributable (as determined under  
9 regulations promulgated by the Secretary) to the  
10 acquisition of equipment and facilities of the hos-  
11 pital, or

12 "(ii) the amount of unexpensed depreciation  
13 attributable (as determined under regulations pro-  
14 mulgated by the Secretary) to the equipment and  
15 facilities of the hospital, less—

16 "(B) the fair market value (as defined by the Sec-  
17 retary) of the equipment and facilities of the hospital;  
18 and

19 "(2) any other expenses (as defined by regulation  
20 by the Secretary) which result from the financial obli-  
21 gation of the applicant being satisfied before due.

22 "(b) The amount of an incentive payment which shall be  
23 made to a hospital, with an approved application under sec-  
24 tion 1642 for the discontinuance of all of its services or the  
25 services of an identifiable unit of the hospital is—

1           “(1) in the case of the discontinuance of all of the  
2       inpatient services of a hospital, an amount not to  
3       exceed the amount reported by the hospital under sec-  
4       tion 1642, and

5           “(2) in the case of the discontinuance of the serv-  
6       ices of an identifiable unit of the hospital, an amount  
7       not to exceed 30 per centum of the charges reported  
8       by the hospital for such unit in the previous hospital  
9       accounting fiscal year pursuant to generally acceptable  
10      accounting principles prescribed by regulations of the  
11      Secretary.

12          “(c) The amount of a conversion payment which shall be  
13      made to a hospital, with an approved application under sec-  
14      tion 1642 is 50 per centum of the reasonable (as determined  
15      by criteria established in regulations of the Secretary) cost of  
16      the conversion approved in such application.

17          “(d) The debt payment, incentive payment, and conver-  
18      sion payment to which a hospital is entitled shall be paid in a  
19      single payment.

20          “(e) The Secretary shall not make a payment pursuant  
21      to this section until the Secretary of Labor has certified that  
22      fair and equitable arrangements have been made to protect  
23      the interests of employees affected by the discontinuance of  
24      services against a worsening of their positions with respect to  
25      their employment including, but not limited to, arrangements

1 to preserve the rights of employees under collective-bargain-  
2 ing agreements; continuation of collective-bargaining rights  
3 consistent with the provisions of the National Labor Rela-  
4 tions Act; reassignment of affected employees to other jobs;  
5 retraining programs; protecting pension, health benefits, and  
6 other fringe benefits of affected employees; and arranging  
7 adequate severance pay, if necessary. Procedures for certifi-  
8 cation by the Secretary of Labor shall conform to standards  
9 established by the Secretary of Labor by regulations.

10       “(f) To make the payments required by this part, there  
11 are authorized to be appropriated \$50,000,000 for the fiscal  
12 year ending September 30, 1980, \$100,000,000 for the fiscal  
13 year ending September 30, 1981, and \$150,000,000 for the  
14 fiscal year ending September 30, 1982.

15                               “STUDY

16       “SEC. 1644. The Secretary shall make a study of the  
17 first twenty-five applications approved under section 1642 to  
18 determine their effect on the elimination of unneeded hospital  
19 services. The Secretary shall report the results of such study  
20 to Congress together with his recommendations for any revi-  
21 sion in the program which he determines to be appropriate,  
22 including any revision in the authorization of appropriations  
23 for such program.”.

1        SEC. 207. Except as provided in section 206, the  
2 amendments made by this title shall take effect on the date of  
3 the enactment of this Act.

4        TITLE III—MISCELLANEOUS AMENDMENTS

5        SEC. 301. Section 314 is amended by repealing subsec-  
6 tions (a), (b), and (c).

7        SEC. 302. Title IX is repealed in its entirety.

8        SEC. 303. The amendments made by this title shall take  
9 effect on the date of the enactment of this Act.



96TH CONGRESS  
1ST SESSION

# S. 230

To amend title VIII of the Public Health Service Act to extend through fiscal year 1980 the program of assistance for nurse training, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JANUARY 25 (legislative day, JANUARY 15), 1979

Mr. JAVITS (for himself, Mr. KENNEDY, Mr. WILLIAMS, Mr. RANDOLPH, Mr. EAGLETON, Mr. CRANSTON, Mr. RIEGLE, Mr. SCHWEIKER, Mr. STAFFORD, Mr. LEVIN, and Mr. DOLE) introduced the following bill; which was read twice and referred to the Committee on Human Resources

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## A BILL

To amend title VIII of the Public Health Service Act to extend through fiscal year 1980 the program of assistance for nurse training, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 TITLE I—NURSE TRAINING

4 SEC. 101. (a) This Act may be cited as the “Nurse  
5 Training Amendments of 1979”.

6 (b) Whenever in this Act (other than section 204) an  
7 amendment or repeal is expressed in terms of an amendment

1 to, or repeal of, a section or other provision, the reference  
2 shall be considered to be made to a section or other provision  
3 of the Public Health Service Act.

4 SEC. 102. Section 801 (relating to authorizations for  
5 construction grants) is amended by—

6 (1) striking “and” after “1977”, and

7 (2) inserting before the period at the end thereof  
8 “and \$4,000,000 for the fiscal year ending September  
9 30, 1980”.

10 SEC. 103. (a) Subsections (a) and (b) of section 805 (re-  
11 lating to loan guarantees and interest subsidies) are each  
12 amended by striking out “1978” and substituting “1980”.

13 (b) Subsection (e) of section 805 is amended by—

14 (1) striking “and” after “1977”, and

15 (2) inserting “and \$1,000,000 for the fiscal year  
16 ending September 30, 1980” after “1978”.

17 SEC. 104. Subsection (f) of section 810 (relating to capi-  
18 tation grants) is amended by—

19 (1) striking “and” after “1977”, and

20 (2) inserting “and \$34,000,000 for the fiscal year  
21 ending September 30, 1980” after “1978”.

22 SEC. 105. The first sentence of subsection (d) of section  
23 820 (relating to special project grants and contracts) is  
24 amended by—

25 (1) striking out “and” after “1977”, and

(2) inserting before the period “, and \$17,000,000 for the fiscal year ending September 30, 1980”.

SEC. 106. Subsection (b) of section 821 (relating to advanced nurse training programs) is amended by—

(1) striking “and” after “1977”, and

(2) inserting before the period “, and \$13,500,000 for the fiscal year ending September 30, 1980”.

SEC. 107. Subsection (e) of section 822 (relating to nurse practitioner programs) is amended by—

(1) striking “and” after “1977”, and

(2) inserting before the period “and \$15,000,000 for the fiscal year ending September 30, 1980”.

SEC. 108. Subsection (b) of section 830 (relating to traineeships) is amended by—

(1) striking “and” after “1977”, and

(2) inserting before the period at the end thereof “and \$15,000,000 for the fiscal year ending September 30, 1980”.

SEC. 109. (a) Subsection (b)(4) of section 835 (relating to loan agreements) is amended by striking out “1978” and substituting “1980”.

(b) Section 837 (relating to authorizations for student loan funds) is amended by—

(1) striking “and” after “1977”,

1           (2) inserting before the period in the first sentence  
2           “and \$25,500,000 for the fiscal year ending September  
3           30, 1980”,

4           (3) striking out “1979” and substituting “the  
5           fiscal year ending September 30, 1981”, and

6           (4) striking out “October 1, 1978” and substitut-  
7           ing “October 1, 1980”.

8           (c)(1) Subsection (a) of section 839 (relating to distribu-  
9           tion of assets) is amended by striking out “September 30,  
10          1980, and not later than September 30, 1977” and substitut-  
11          ing “September 30, 1981, and not later than December 30,  
12          1983”.

13          (2) Paragraph (1) of such subsection is amended by  
14          striking out “1980” and substituting “1983”.

15          (3) Subsection (b) of such section is amended by striking  
16          out “1980” each place it occurs and substituting “1983”.

17          SEC. 110. (a) Subsection (b) of section 845 (relating to  
18          scholarship grants) is amended by—

19               (1) striking out “next two fiscal years” in the first  
20               sentence and substituting “next four fiscal years”,

21               (2) striking out “1979” and substituting “1981”,  
22               and

23               (3) striking out “1978” and substituting “1980”.

24          (b) Subsection (c)(1) of such section is amended by—

(1) striking out "next two fiscal years" in subparagraph (A) and substituting "next four fiscal years",

(2) striking out "1978" in subparagraph (B) and substituting "1980", and

(3) striking out "1979" in subparagraph (B) and substituting "1981".

SEC. 111. Section 836 (b)(3) (relating to student loans) is amended by—

(1) inserting after "(3)" the following: "in the case of a student who received such a loan before the date of enactment of the Nurse Training Amendments of 1979", and

(2) striking out "any such loan" and substituting "any such loan made before the date of enactment of the Nurse Training Amendments of 1979".

SEC. 112. (a) The Secretary of Health, Education, and Welfare (hereinafter in this section referred to as the "Secretary") shall arrange, in accordance with subsection (b), for the conduct of a study to determine the need to continue a specific program of Federal financial support for nursing education, taking into account—

(1) the need for nurses under the present health care delivery system and under that system as it may be changed by the enactment of legislation for national health insurance,

1           (2) the cost of nursing education, and

2           (3) the availability of other sources of support for  
3       nursing education, including support under general pro-  
4       grams of Federal financial support for postsecondary  
5       education, under State and other public programs, and  
6       from private sources.

7       (b)(1) The Secretary shall first request the National  
8       Academy of Sciences (hereinafter in this section referred to  
9       as the "Academy"), acting through the Institute of Medicine,  
10      to conduct the study required by subsection (a), under an  
11      arrangement whereby the actual expenses incurred by the  
12      Academy directly related to the conduct of such study will be  
13      paid by the Secretary. If the Academy agrees to such re-  
14      quest, the Secretary shall enter into such an agreement with  
15      the Academy.

16       (2) If the Academy declines the Secretary's request to  
17      conduct such study under such an arrangement, then the  
18      Secretary shall enter into a similar arrangement with another  
19      appropriate public or nonprofit private entity to conduct such  
20      study.

21       (3) Upon completion of the study, the entity conducting  
22      the study shall provide a report of the results to the Secre-  
23      tary and shall include in such report any recommendations  
24      for legislation which the entity determines are appropriate.

1       (4) Any arrangement entered into under paragraph (1)  
2 or (2) of this subsection for the conduct of a study shall re-  
3 quire that such study be completed and reports thereon be  
4 submitted within such period as the Secretary may require to  
5 meet the requirements of subsection (c).

6       (c) Not later than January 15, 1980, the Secretary shall  
7 report to the Committee on Human Resources of the Senate  
8 and the Committee on Interstate and Foreign Commerce of  
9 the House of Representatives the results of the study con-  
10 ducted pursuant to subsection (a) together with such recom-  
11 mendations for legislation as the Secretary determines are  
12 appropriate.

## 13       TITLE II—OTHER HEALTH PROFESSIONS

### 14                               PROGRAMS

15       SEC. 201. Section 729(a) (relating to limits on Federal  
16 loan insurance and insured loans) is amended by—

17               (1) inserting before the period in the first sentence  
18 a comma and the following: “except that in the case of  
19 loans to students in schools of medicine, osteopathy,  
20 and dentistry, the Secretary may increase the total of  
21 such loans which may be covered by Federal loan in-  
22 surance to \$15,000 if he determines that the costs of  
23 education at such schools requires such increase”; and

24               (2) inserting before the period in the second sen-  
25 tence a comma and the following: “except that the

1 Secretary may increase such amount for borrowers  
2 who are or were students in schools of medicine, oste-  
3 opathy, and dentistry to \$60,000 if he determines that  
4 the costs of education at such schools requires such in-  
5 crease”.

6 SEC. 202. Section 752(b)(5)(A) (relating to service re-  
7 quirements for National Health Service Corps scholarships)  
8 is amended by striking out “(not to exceed three years)” and  
9 substituting “(not to exceed three years or such greater  
10 period as the Secretary, consistent with the needs of the  
11 Corps, may authorize)”.

12 SEC. 203. Section 781(c) (relating to requirements for  
13 participation of schools in area health education center pro-  
14 grams) is amended by adding after and below paragraph (4)  
15 the following:

16 “The requirement of paragraph (3) shall not apply to a medi-  
17 cal or osteopathic school participating in an area health edu-  
18 cation center program if another such school participating in  
19 the same program meets the requirement of that para-  
20 graph.”.

21 SEC. 204. Section 802(a) of the Health Professions  
22 Educational Assistance Act of 1976 (relating to transitional  
23 provisions on area health education centers) is amended by—

24 (1) striking out “for the next fiscal year” and sub-  
25 stituting “for the next three fiscal years”;



1           (2) striking out "no payment shall be made to an  
2       entity under such a contract" and substituting "no  
3       payment under such a contract shall be made to an  
4       entity which had not first entered into such a contract  
5       before October 12, 1976, (1)"; and

6           (3) inserting before the period at the end thereof:  
7       ", or (2) for any fiscal year beginning after September  
8       30, 1979".

9       SEC. 205. Subparagraph (B) of section 788(e)(2) is  
10   amended by striking out "\$5,000,000" and substituting  
11   "\$10,000,000".

**S. 590**

IN THE SENATE OF THE UNITED STATES

Mr. JAVITS (for himself, Mr. KENNEDY, Mr. WILLIAMS, Mr. RANDOLPH, Mr. STAFFORD, Mr. RIEGLE, and Mr. INOUE) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

# A BILL

To amend the Public Health Service Act to revise and strengthen the program under that Act for the regulation of clinical laboratories.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,  
That this Act may be cited as the “Clinical Laboratory Improvement Act of 1979”.

## FINDINGS

6 SEC. 2. The Congress finds that—

II-E

1           (1) clinical laboratory testing is a vital element of  
2 health care throughout the Nation;

3           (2) health care in this Nation will only be effective  
4 and of high quality if procedures utilized for testing by  
5 clinical laboratories assure accurate and reliable re-  
6 sults;

7           (3) it is essential to the public interest that the  
8 health and welfare of consumers of health care be pro-  
9 tected by requiring that all clinical laboratories comply  
10 with uniform standards to assure accurate and reliable  
11 testing by laboratories;

12           (4) testing in clinical laboratories which do not  
13 comply with such standards can be performed at less  
14 expense and thus such laboratories are able to compete  
15 unfairly with the clinical laboratories which do comply  
16 with such standards;

17           (5) requiring compliance with standards to assure  
18 accurate and reliable testing by clinical laboratories  
19 which operate in interstate commerce without provision  
20 for requiring compliance with such standards by other  
21 clinical laboratories will discriminate against and de-  
22 press interstate commerce and adversely burden,  
23 obstruct, and affect such commerce;

1           (6) all clinical laboratory testing is either in inter-  
2           state commerce or substantially affects such commerce;  
3           and

4           (7) consequently, regulation by the Secretary in  
5           cooperation with the States as contemplated by the  
6           amendment made by this Act is appropriate to prevent  
7           and eliminate burdens upon interstate commerce, to ef-  
8           fectively regulate interstate commerce, and to protect  
9           the health and welfare of consumers of health care.

10       AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT

11       SEC. 3. (a) Part H of title III of the Public Health  
12       Service Act is amended to read as follows:

13               "PART H—CLINICAL LABORATORIES

14                       "DEFINITIONS

15       "SEC. 370. As used in this part—

16               "(1) The terms 'laboratory' and 'clinical labora-  
17       tory' mean (A) a facility for the biological, microbiolog-  
18       ical, serological, chemical, immuno-hematological, ra-  
19       dioimmunological, hematological, biophysical, cytologi-  
20       cal, pathological, or other examination of materials de-  
21       rived from the human body for the purpose of provid-  
22       ing information for the diagnosis, prevention, or treat-  
23       ment of any disease or impairment of, or the assess-  
24       ment of the health of, humans, or (B) a facility for the  
25       collection, processing, and transmission of such materi-

als for such purposes, other than a facility exclusively engaged in the collection or processing of human blood or its components intended for transfusion or further manufacturing.

“(2) The term ‘interstate commerce’ means trade, traffic, commerce, transportation, transmission, or communication between any State, territory, or possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

#### “LICENSES

“SEC. 371. (a) The Secretary shall establish and have in effect within twenty-four months after the date of enactment of this section a system for the licensure of all clinical laboratories subject to national standards in effect under section 372. A clinical laboratory subject to the national standards in effect under section 372 shall not perform any tests or provide any services thirty-six months after the date of enactment of this section unless such laboratory has in effect a valid license issued under this section. A license issued under such system for a clinical laboratory (1) shall specify the categories of tests and procedures which such laboratory may perform, and (2) shall be valid for such period as the Secretary may prescribe not in excess of twenty-four months. A clinical laboratory may, at the discretion of the Secretary,

1 perform tests and provide services during the period its appli-  
2 cation for a license is pending.

3 “(b) The system established under subsection (a) shall  
4 require the following as a condition to the issuance or renew-  
5 al of a license under the system:

6 “(1) the submission of an application in such form  
7 and manner as may be prescribed by the Secretary,  
8 and

9 “(2) a determination by the Secretary that the ap-  
10 plicant meets the national standards in effect under  
11 section 372.

12 “(c)(1) If the Secretary finds, after reasonable notice  
13 and opportunity for a hearing, that—

14 “(A) a clinical laboratory licensed under this sub-  
15 section is not in compliance with applicable national  
16 standards in effect under section 372, or

17 “(B) such laboratory has (i) failed to comply with  
18 reasonable requests of the Secretary for any informa-  
19 tion, specimens, or tests on specimens, as the Secre-  
20 tary deems necessary to determine the laboratory’s  
21 continued eligibility for its license under this subsection  
22 or continued compliance with applicable national stand-  
23 ards in effect under section 372, or (ii) refused a re-  
24 quest of the Secretary or any officer, employee, or  
25 agent duly designated by him for permission to inspect

1 or monitor the laboratory and its operations, speci-  
2 mens, and relevant records at any reasonable time,  
3 the Secretary may revoke such laboratory's license for the  
4 remainder of its term or may limit or suspend such laborato-  
5 ry's license until such laboratory has demonstrated to the  
6 satisfaction of the Secretary that the laboratory is in compli-  
7 ance with such national standards or such requests will be  
8 complied with, as the case may be.

9 “(2) If the Secretary finds, after reasonable notice and  
10 opportunity for a hearing (in accordance with the procedures  
11 specified in section 1869(c) of the Social Security Act), that a  
12 clinical laboratory licensed under this section—

13 “(A) has been guilty of misrepresentation in ob-  
14 taining the license;

15 “(B) has engaged or attempted to engage in, or  
16 represented itself as entitled to perform, any laboratory  
17 test or procedure or category of tests or procedures not  
18 authorized by the license;

19 “(C) has engaged in a billing practice under which  
20 charges for laboratory services provided a patient, on  
21 whose behalf reimbursement (in whole or in part) for  
22 such charges is provided funds under any Federal pro-  
23 gram, are made at a higher rate than charges for com-  
24 parable services provided a patient for whom such  
25 reimbursement is not made;

1           “(D) has offered, paid, solicited, or received any  
2       kickback, bribe, finder’s fee, rebate, or other illegal re-  
3       muneration but excluding any discount or other reduc-  
4       tion in price and excluding any amount paid by an em-  
5       ployer for employment in the provision of the services,  
6       directly or indirectly, overtly or covertly, in cash or in  
7       kind in connection with the provision of clinical labora-  
8       tory services; or

9           “(E) has engaged in any false, fictitious, or fraud-  
10      ulent billing practice for the purposes of obtaining pay-  
11      ment under any program the funds for which are pro-  
12      vided in whole or in part by the United States,  
13      the Secretary may revoke such license for the remainder of  
14      its term or may make the laboratory or any person deter-  
15      mined by the Secretary to have made the misrepresentation  
16      described in subparagraph (A) or to have engaged in any ac-  
17      tivity described in subparagraph (B), (C), (D), or (E) ineligible  
18      to apply for a license under this subsection for such period  
19      (not to exceed twenty-four months) as the Secretary may  
20      prescribe, or take both such actions. A billing practice which  
21      results in different charges for the same laboratory services  
22      solely because of differences in administrative costs related to  
23      receiving reimbursement for the provision of such services  
24      shall not be considered a billing practice described in subpar-  
25      agraph (C).



1       “(3) Any person who is convicted under section 375 or  
2 under section 1877 or 1909 of the Social Security Act after  
3 the date of enactment of the Clinical Laboratory Improve-  
4 ment Act of 1979 for a violation occurring after such date  
5 shall not be eligible to apply for a license under this subsec-  
6 tion for a clinical laboratory during the ten-year period begin-  
7 ning on the date of such person’s judgment of conviction.  
8 Where the person so convicted has a direct or indirect own-  
9 ership or control interest of 5 per centum or more in the  
10 laboratory involved in such violation, or is an officer, direc-  
11 tor, agent, or managing employee (as defined in section  
12 1126(b) of the Social Security Act) of such laboratory, the  
13 Secretary may revoke the license of such laboratory.

14                               “NATIONAL STANDARDS

15       “SEC. 372. (a) Within one year after the date of the  
16 enactment of the Clinical Laboratory Improvement Act of  
17 1979, the Secretary shall publish proposed national standards  
18 for clinical laboratories. Within one hundred and eighty days  
19 after such standards are proposed, the Secretary shall pro-  
20 mulgate such standards with such modifications as the Secre-  
21 tary deems appropriate and such standards shall take effect  
22 upon their promulgation. Standards under this subsection may  
23 be amended by the Secretary.

24       “(b) National standards promulgated under subsection  
25 (a) for clinical laboratories, designed to assure consistent per-

1 performance by clinical laboratories of accurate and reliable lab-  
2 oratory tests and other procedures and services, shall—

3       “(1) require clinical laboratories subject to the  
4 standards to maintain appropriate quality control pro-  
5 grams,

6       “(2) require such laboratories to maintain such  
7 records, equipment, and facilities as may be necessary  
8 for the proper and effective operation of such  
9 laboratories,

10       “(3) require satisfactory performance by such lab-  
11 oratories based upon periodic proficiency tests devel-  
12 oped in accordance with subsection (d)(3),

13       “(4) to the extent necessary to insure the accura-  
14 cy and reliability of the performance of tests and serv-  
15 ices by such laboratories, prescribe qualifications for di-  
16 rectors and supervisory personnel of, and laboratory  
17 technical personnel employed in, such laboratories  
18 which qualifications shall (A) not be limited solely to  
19 education requirements but shall include, where appro-  
20 priate, training, experience, and examination require-  
21 ments, (B) include requirements designed to insure the  
22 continued competence of laboratory personnel, and (C)  
23 take into account advances in the sciences and im-  
24 provements in the technology utilized in laboratory  
25 testing which may require specialty personnel,

1           “(5) contain adequate provisions for inspecting  
2       laboratories and enforcing and monitoring the enforce-  
3       ment of standards, and

4           “(6) include such other requirements as the Secre-  
5       tary determines necessary to assure consistent perform-  
6       ance by such laboratories of accurate and reliable tests  
7       and other procedures and services.

8           “(c) Standards prescribed under subsection (b) for clini-  
9       cal laboratories may vary on the basis of the type of tests,  
10      procedures, or services performed by such laboratories or the  
11      purposes for which such tests, procedures, or services are  
12      performed.

13          “(d) Within one year after the date of the enactment of  
14      the Clinical Laboratory Improvement Act of 1979, the Sec-  
15      retary, in consultation with appropriate professional organi-  
16      zations, shall—

17           “(1) develop job-related proficiency and practical  
18      examinations (including reasonable standards for deter-  
19      mining successful completion of such examinations) as  
20      determined necessary by the Secretary for personnel in  
21      clinical laboratories which examinations reflect the  
22      nature of the work performed by such personnel,

23           “(2) develop mechanisms designed to assure the  
24      continued competence of such personnel, and

1           “(3) develop standards for the proficiency testing  
2       of clinical laboratories which standards—

3           “(A) shall require such tests to be adminis-  
4       tered at least annually to all laboratories subject  
5       to the national standards in effect under subsec-  
6       tion (a);

7           “(B) shall require a system of onsite testing,  
8       including supervised unannounced onsite testing,  
9       of the proficiency of a laboratory in the examina-  
10      tion of specimens; and

11          “(C) may require a system for the testing of  
12      a laboratory’s proficiency in the examination of  
13      specimens under which system the laboratory is  
14      not informed that its proficiency is being tested  
15      (commonly referred to as ‘blind proficiency  
16      testing’).

17          “(c) The examinations developed under paragraph (1) of  
18      subsection (d) shall be required to be administered only  
19      during the twenty-four-month period immediately following  
20      the initial administration of such examinations.

21          “(f)(1) National standards for clinical laboratories in  
22      effect under section 372 shall be administered and enforced  
23      by the Secretary and shall, except as provided in this subsec-  
24      tion, apply to each clinical laboratory which is engaged in  
25      commerce.

1       “(2) During the two-year period beginning on the date  
2 that national standards for clinical laboratories first take  
3 effect under section 372 the provisions of such standards pre-  
4 scribing qualifications for laboratory personnel shall not apply  
5 to a clinical laboratory which—

6           “(A) the Secretary determines is located in a  
7 rural area (as defined by the Secretary) in which indi-  
8 viduals with the qualifications prescribed by such provi-  
9 sions are not available,

10          “(B) performs services solely for hospitals and li-  
11 censed physicians, dentists, or podiatrists (or any com-  
12 bination of such practitioners) located within such a  
13 rural area, and

14          “(C) provides the Secretary satisfactory assur-  
15 ances that it will take such actions as may be neces-  
16 sary to train individuals to meet such qualifications or  
17 to employ individuals with such qualifications.

18       “(3)(A) Upon such conditions as the Secretary may by  
19 regulation prescribe, the Secretary may exempt from the na-  
20 tional standards for clinical laboratories any clinical  
21 laboratory—

22           “(i) which is located in the office of, and operated  
23 by, a licensed physician, dentist, or podiatrist, or a  
24 group of not more than five such practitioners, or in a

1 rural health clinic, as defined in section 1861(aa)(22) of  
2 the Social Security Act, and

3 “(ii) in which the only tests or procedures which  
4 are performed are routine tests or procedures (as deter-  
5 mined by the Secretary) performed by such a practi-  
6 tioner or clinic in connection with the treatment of the  
7 patients of such practitioner (or practitioners) or clinic.

8 “(B) If the Secretary finds, after reasonable notice, that  
9 a laboratory granted an exemption under subparagraph (A) is  
10 not a laboratory which is described by clauses (i) and (ii) of  
11 subparagraph (A) or that such laboratory has engaged in mis-  
12 representation in obtaining the exemption, the Secretary  
13 shall withdraw the exemption granted such laboratory.

14 “(C) The national standards for clinical laboratories may  
15 not apply to any clinical laboratory described in subpara-  
16 graph (A)(i) if the laboratory successfully participates in a  
17 proficiency-testing program approved by the Secretary and if  
18 the laboratory has submitted to the Secretary in accordance  
19 with this paragraph notice of its participation in such a pro-  
20 gram. The notice required by this paragraph shall be made in  
21 such form and manner as the Secretary shall prescribe. The  
22 Secretary may not approve a proficiency testing program for  
23 purposes of this paragraph unless the program operator has  
24 entered into an agreement with the Secretary to provide in-

1 formation to the Secretary respecting the results of the profi-  
2 ciency tests administered under such program.

3 “(D) The Secretary shall exempt, on such terms and  
4 conditions as may be appropriate, from the national standards  
5 for clinical laboratories any laboratory in which the tests or  
6 procedures which are performed are primarily tests or proce-  
7 dures for biomedical or behavioral research.

8 “(E) The Secretary shall exempt, on such terms and  
9 conditions as may be appropriate, from the national standards  
10 for clinical laboratories any laboratory in which the only tests  
11 or procedures performed are tests or procedures for persons  
12 engaged in the business of insurance solely for the purpose of  
13 determining whether to write an insurance contract or deter-  
14 mining eligibility for payments under an insurance contract.

15 “(4) Any clinical laboratory in interstate commerce  
16 shall, during the period beginning on the date of the enact-  
17 ment of the Clinical Laboratory Improvement Act of 1979,  
18 and ending on the date such laboratory is required to have in  
19 effect a license issued under this section, comply with the  
20 licensing requirements in effect under section 353 prior to the  
21 date of enactment of the Clinical Laboratory Improvement  
22 Act of 1979.

23 “AGREEMENTS

24 “SEC. 373. (a) The Secretary may enter into agree-  
25 ments with qualified nonprofit private entities which, as de-

1 terminated by the Secretary, have adopted and implemented  
2 laboratory standards at least as stringent as those in effect  
3 under section 372, under which agreements such entities  
4 shall make such inspections as the Secretary may require to  
5 determine if clinical laboratories are in compliance with ap-  
6 plicable standards, administer such proficiency tests as the  
7 Secretary may require for clinical laboratories, or administer  
8 such examinations of laboratory personnel as the Secretary  
9 may require.

10       “(b) Where a State agency or local agencies demon-  
11 strate that sufficient qualified personnel are available to them  
12 to permit the effective enforcement of this part, and in the  
13 case of any State which has an agreement with the Secretary  
14 under section 1864 of the Social Security Act with respect to  
15 clinical laboratories, the Secretary shall amend such agree-  
16 ment with respect to any such State which is able and willing  
17 to do so to provide that the State agency or local agencies  
18 which are utilized under such agreement with respect to  
19 clinical laboratories will be utilized for the purpose of deter-  
20 mining whether clinical laboratories in such State meet the  
21 requirements for a license under section 371.

22               “FEDERAL CLINICAL LABORATORIES

23       “SEC. 374. (a) Federal clinical laboratories under the  
24 jurisdiction of the Secretary shall be subject to national  
25 standards in effect under section 372 and any other Federal



1 clinical laboratory in a State shall be subject to such stand-  
2 ards unless (1) the laboratory is under the jurisdiction of any  
3 of the Armed Forces of the United States or the Administra-  
4 tor of Veterans' Affairs, or (2) the agency which has jurisdic-  
5 tion over such laboratory has in effect standards for such lab-  
6 oratory which are no less stringent than the national stand-  
7 ards in effect under section 372.

8       “(b) The Secretary shall bring the national standards in  
9 effect under section 372 to the attention of the Secretary of  
10 each military department and the Administrator of Veterans'  
11 Affairs so that such standards may be considered and applied,  
12 as appropriate, by such Secretaries and Administrator to  
13 clinical laboratories under their jurisdiction.

14                       “PROHIBITED ACTS; REMEDIES

15       “SEC. 375. (a) Whoever—

16               “(1) knowingly and willfully solicits, or knowingly  
17 and willfully accepts, directly or indirectly, any speci-  
18 men for a laboratory test or other laboratory procedure  
19 by a clinical laboratory which is required to have in  
20 effect a license issued under section 371 and which  
21 does not have such a license in effect or which is not  
22 authorized by its license to perform such test procedure  
23 shall be fined not more than \$25,000 or imprisoned for  
24 more than five years, or both; or

1           “(2)(A) knowingly and willfully makes or causes  
2       to be made any false statement or representation of a  
3       material fact in any application for a license under this  
4       part;

5           “(B) having knowledge of the occurrence of any  
6       event affecting the initial or continued right to any  
7       such license, conceals or fails to disclose such event  
8       with an intent fraudulently to secure or hold such  
9       license when no license is authorized; or

10          “(C) having made application to receive a license  
11       for a specific use and having received it, knowingly  
12       and willfully converts such license to an unauthorized  
13       use,

14 shall—

15          “(i) in the case of such a statement, representa-  
16       tion, concealment, failure, or conversion by any person  
17       in connection with the obtaining of a license, be guilty  
18       of a felony and upon conviction thereof fined not more  
19       than \$25,000 or imprisoned for not more than five  
20       years or both, or

21          “(ii) in the case of such a statement, representa-  
22       tion, concealment, failure, or conversion by any other  
23       person, be guilty of a misdemeanor and upon convic-  
24       tion thereof fined not more than \$10,000 or imprisoned  
25       for not more than one year, or both.

1       “(b)(1) Whoever solicits or receives any remuneration  
2 (including any kickback, bribe, or rebate) directly or indirect-  
3 ly, overtly or covertly, in cash or in kind—

4           “(A) in return for referring an individual to a  
5 person for the furnishing or arranging for the furnish-  
6 ing of any item or service described in this part; or

7           “(B) in return for purchasing, leasing, ordering, or  
8 arranging for or recommending purchasing, leasing, or  
9 ordering any goods, facility, service, or items described  
10 in this part,

11 shall be guilty of a felony and upon conviction thereof, shall  
12 be fined not more than \$25,000 or imprisoned for not more  
13 than five years, or both.

14       “(2) Whoever offers or pays any remuneration (includ-  
15 ing any kickback, bribe, or rebate) directly or indirectly,  
16 overtly or covertly, in cash or in kind to any person to induce  
17 such person—

18           “(A) to refer an individual to a person for the fur-  
19 nishing or arranging for the furnishing of any item or  
20 service described in this part, or

21           “(B) to purchase, lease, order, or arrange for or  
22 recommend purchasing, leasing, or ordering any goods,  
23 facility, service, or item described in this part,

1 shall be guilty of a felony and upon conviction thereof, shall  
2 be fined not more than \$25,000 or imprisoned for not more  
3 than 5 years, or both.

4 “(3) Paragraphs (1) and (2) shall not apply to—

5 “(A) a discount or other reduction in price ob-  
6 tained by a provider of services or other entity under  
7 this title if the reduction in price is properly disclosed  
8 and appropriately reflected in the costs claimed or  
9 charges made by the provider or entity under this part;  
10 and

11 “(B) any amount paid by an employer to an em-  
12 ployee (who has a bona fide employment relationship  
13 with such employer) for employment in the provision of  
14 covered items or services.

15 “(c) Whenever the Secretary has reason to believe that  
16 continuation of any activity by a clinical laboratory required  
17 to be licensed under this section by the Secretary would con-  
18 stitute a substantial risk to the public health, he or she may  
19 bring suit in the United States district court for the district in  
20 which such laboratory is situated to enjoin continuation of  
21 such activity and, upon proper showing, a temporary injunc-  
22 tion or restraining order against continuation of such activity  
23 pending issuance of a final order by the court shall be granted  
24 without bond.

1       “(d)(1) No employer may discharge any employee or  
2 otherwise discriminate against any employee with respect to  
3 the employee’s compensation or the terms, conditions, or  
4 privileges of his employment solely because the employee (or  
5 any person acting pursuant to a request of the employee)  
6 has—

7       “(A) commenced or caused to be commenced, or  
8 is about to commence or cause to be commenced a pro-  
9 ceeding under this part;

10       “(B) testified or is about to testify in any such  
11 proceeding; or

12       “(C) assisted or participated or is about to assist  
13 or participate in any manner in such a proceeding or in  
14 any other action to carry out the purposes of this part.

15       “(2)(A) Any employee who believes that he or she has  
16 been discharged or otherwise discriminated against by any  
17 person in violation of paragraph (1) may, within sixty days  
18 after such alleged violation occurs, file (or have any person  
19 file on the employee’s behalf) a complaint with the Secretary  
20 of Labor alleging such discharge or discrimination. Such  
21 sixty-day period shall be tolled during the pendency of any  
22 grievance procedures or other efforts at conference, concilia-  
23 tion, or mediation. Upon receipt of such a complaint, the Sec-  
24 retary of Labor shall notify the person named in the com-  
25 plaint of the filing of the complaint.

1       “(B)(i) Upon receipt of a complaint filed under subpara-  
2 graph (A), the Secretary of Labor shall conduct an investiga-  
3 tion of the violation alleged in the complaint. Within thirty  
4 days of the receipt of such complaint, the Secretary of Labor  
5 shall complete such investigation and shall notify the com-  
6 plainant (and any person acting with the authority of the  
7 complainant) and the person alleged to have committed such  
8 violation of the results of the investigation conducted pursu-  
9 ant to this subparagraph. Within ninety days of the receipt of  
10 such complaint the Secretary of Labor shall, unless the pro-  
11 ceeding on the complaint is terminated by the Secretary of  
12 Labor on the basis of a settlement entered into by the Secre-  
13 tary of Labor and the person alleged to have committed such  
14 violation, issue an order either providing the relief prescribed  
15 by clause (ii) or dismissing the complaint. An order of the  
16 Secretary of Labor providing for the relief prescribed by  
17 clause (ii) shall be made on the record after notice and oppor-  
18 tunity for agency hearing. The Solicitor of Labor shall, with  
19 the consent of the employee, represent such employee at any  
20 such hearing.

21       “(ii) If in response to a complaint filed under subpara-  
22 graph (A) the Secretary of Labor determines that a violation  
23 of paragraph (1) has occurred, the Secretary of Labor shall  
24 order (I) the person who committed such violation to take  
25 affirmative action to abate the violation, (II) such person to

1 reinstate the complainant to the complainant's former posi-  
2 tion together with the compensation (including back pay),  
3 terms, conditions, and privileges of the complainant's em-  
4 ployment, (III) the award of compensatory damages, and  
5 (IV) where appropriate, the award of exemplary damages. If  
6 such an order is issued, the Secretary, at the request of the  
7 complainant, shall assess against the person against whom  
8 the order is issued a sum equal to the aggregate amount of  
9 all costs and expenses (including attorney's fees) reasonably  
10 incurred, as determined by the Secretary of Labor, by the  
11 complainant for, or in connection with, the bringing of the  
12 complaint upon which the order was issued.

13       “(3)(A) Any employee or employer adversely affected or  
14 aggrieved by an order issued under paragraph (2) may obtain  
15 review of the order in the United States court of appeals for  
16 the circuit in which the violation, with respect to which the  
17 order was issued, allegedly occurred. The petition for review  
18 must be filed within sixty days from the issuance of the final  
19 order. Review shall conform to chapter 7 of title 5 of the  
20 United States Code.

21       “(B) An order of the Secretary of Labor, with respect to  
22 which review could have been obtained under subparagraph  
23 (A), shall not be subject to judicial review in any criminal or  
24 other civil proceeding.

1       “(4) Whenever a person has failed to comply with an  
2 order issued under paragraph (2)(B), the Secretary of Labor  
3 shall file a civil action in the United States district court for  
4 the district in which the violation was found to occur to en-  
5 force such order. In actions brought under this paragraph,  
6 the district courts of the United States shall have jurisdiction  
7 to grant all appropriate relief, including injunctive relief and  
8 compensatory and exemplary damages.

9       “(5) Paragraph (1) shall not apply with respect to any  
10 employee who, acting without direction from his or her em-  
11 ployer (or any agent of the employer), deliberately causes a  
12 violation of any requirement of this section.

13                               “ADMINISTRATION

14       “SEC. 376. (a) The Secretary shall designate a Director  
15 of Clinical Laboratories who shall serve at the pleasure of the  
16 Secretary.

17       “(b) The Secretary, acting through the designated Di-  
18 rector of Clinical Laboratories, shall have responsibility—

19               “(1) to establish a uniform regulatory policy for  
20 the administration of the functions authorized under  
21 this part and the laboratory certification and regulatory  
22 functions presently administered under this Act, the  
23 Federal Food, Drug, and Cosmetic Act, and titles  
24 XVIII and XIX of the Social Security Act,



1           “(2) to provide guidance with respect to the labo-  
2       ratory component of other health programs adminis-  
3       tered and enforced by the Secretary,

4           “(3) to improve laboratory methodology and utili-  
5       zation promotion and funding of grant and contract  
6       projects and studies, both solicited and unsolicited.

7           “TECHNICAL ASSISTANCE

8       “SEC. 377. (a) The Secretary shall provide technical  
9       assistance to States to assist in carrying out the requirements  
10      of this part. Such assistance shall include—

11           “(1) training of State laboratory personnel (includ-  
12      ing the provision of instructional materials and equip-  
13      ment) where necessary to qualify such persons for the  
14      enforcement of this part;

15           “(2) monitoring of the adequacy of State enforce-  
16      ment of this part through a program of followup Feder-  
17      al inspections and testing of laboratories inspected and  
18      tested by State personnel or by organizations designat-  
19      ed by the Secretary to inspect and test laboratories  
20      under this part.

21           “(b) The Secretary shall provide for technical assistance  
22      to laboratories. Such assistance shall include a program of  
23      technical consultations and technical training for employees  
24      of laboratories which have deficiencies documented through  
25      evaluation programs such as proficiency tests.

1       “(c) The Secretary is authorized to make grants to and  
2 enter into contracts with public and nonprofit private entities  
3 for projects and studies respecting clinical laboratory method-  
4 ology and utilization. No grant may be made or contract en-  
5 tered into under this subsection unless an application therefor  
6 has been submitted to and approved by the Secretary. Such  
7 application shall be submitted in such form and contain such  
8 information as the Secretary may reasonably require.

9       “(d) There are authorized to be appropriated for the  
10 purposes of this section \$10,000,000 for the fiscal year  
11 ending September 30, 1981, \$10,000,000 for the fiscal year  
12 ending September 30, 1982, and \$10,000,000 for the fiscal  
13 year ending September 30, 1983.

14                               “ANNUAL REPORT

15       “SEC. 378. Not later than January 1, 1981, and Janu-  
16 ary 1 of each succeeding year the Secretary shall make a  
17 report to the Congress (1) respecting the accuracy and reli-  
18 ability of tests and procedures performed by clinical laborato-  
19 ries during the preceding fiscal year, and (2) evaluating the  
20 effect of the costs and pricing of clinical laboratory tests and  
21 procedures on the overall cost of health care services and the  
22 relation of the costs of such tests and procedures to the costs  
23 of the health care services for which the tests and procedures  
24 are conducted.

1           “STUDIES RESPECTING REQUIREMENTS FOR  
2           LABORATORIES AND LABORATORY PERSONNEL

3           “SEC. 379. (a) The Secretary, in cooperation with ap-  
4   propriate public and private entities, shall conduct studies of  
5   (1) existing voluntary certification standards and State licen-  
6   sure laws for clinical laboratory supervisors, technologists,  
7   and technicians, (2) qualifications of entities that certify such  
8   personnel as qualified to perform laboratory procedures in  
9   clinical laboratories licensed under section 353 of the Public  
10   Health Service Act, (3) existing and proposed public and pri-  
11   vate mechanisms to determine the continued competence of  
12   such personnel, (4) existing laboratory proficiency testing  
13   methods used to evaluate the performance of clinical labora-  
14   tories, and (5) the relationship of requirements for such per-  
15   sonnel and of clinical laboratory proficiency testing require-  
16   ments with clinical laboratory performance.

17          “(b) The studies required by subsection (a) shall in-  
18   clude—

19               “(1) an assessment of the need for certification of  
20   such personnel pursuant to national standards and for  
21   assurance of their continued competence;

22               “(2) development of national standards which the  
23   Secretary determines should be used as guidelines for  
24   entities which certify such laboratory personnel with

1 consideration of the need for increased geographic and  
2 career mobility of such personnel;

3 “(3) a determination of the numbers of technical  
4 laboratory personnel who would meet standards devel-  
5 oped by the Secretary under paragraph (2) and a pro-  
6 jection of the numbers of such personnel in the calen-  
7 dar years 1982, 1986, and 1990;

8 “(4) an analysis and evaluation of the effect on  
9 the costs of laboratory tests and procedures and quality  
10 of such tests and procedures of a requirement that a  
11 laboratory may not be licensed under this part unless  
12 its personnel meet standards developed by the Secre-  
13 tary under paragraph (2);

14 “(5) an analysis and evaluation of the problems  
15 encountered by rural clinical laboratories in recruiting  
16 qualified personnel; and

17 “(6) an analysis and evaluation of the perform-  
18 ance of the laboratories located in the office of a prac-  
19 titioner and the advisability of continuing in effect the  
20 exemption procedure authorized under section  
21 372(d)(3)(A).

22 “(c) Within three years of the date of the enactment of  
23 this Act the Secretary shall submit to the Congress the re-  
24 sults of the studies conducted pursuant to subsection (a) and

1 recommendations for legislation which the Secretary consid-  
2 ers necessary.

3 "REIMBURSEMENT BY SECRETARY

4 "SEC. 379A. (a) The Secretary shall reimburse to the  
5 Federal Hospital Insurance Trust Fund and the Federal Sup-  
6 plementary Medical Insurance Trust Fund any amount ex-  
7 pended from such funds under the provisions of section 371  
8 or under an agreement entered into under section 1864 of the  
9 Social Security Act, which was expended with respect to a  
10 clinical laboratory which does not participate in the program  
11 of health insurance for the aged and disabled under title  
12 XVIII of the Social Security Act."

13 (b) Subpart 2 of part F of title III of the Public Health  
14 Service Act is repealed.

15 REPORT ON EXEMPTIONS

16 SEC. 4. The Secretary of Health, Education, and Wel-  
17 fare shall report to the Congress with respect to such labora-  
18 tories as may be exempt from the requirements of standards  
19 established pursuant to section 372 during the three-year  
20 period beginning on the date national standards take effect  
21 under section 372 and, on the basis of such report, make  
22 recommendations (1) as to whether clinical laboratories  
23 granted exemptions under section 372 should be required, as  
24 a condition to their exemption, to have laboratory procedure  
25 manuals, participate in laboratory proficiency testing pro-

1 grams, and maintain quality control programs prescribed  
2 under such standards, and (2) as to whether such section 372  
3 should otherwise be revised. Such report shall be submitted  
4 within 3 months of the expiration of such period.

5 AMENDMENTS RELATING TO CERTIFICATION OF CLINICAL  
6 LABORATORIES

7 SEC. 5. (a)(1) The second sentence of section 1861(s) of  
8 the Social Security Act is amended to read as follows: "No  
9 diagnostic test performed in any laboratory shall be included  
10 in paragraph (3) unless such laboratory is licensed under sec-  
11 tion 371 of the Public Health Service Act, or if the licensing  
12 requirements under that section are not applicable, meets  
13 such conditions relating to the health and safety of individ-  
14 uals with respect to whom such tests are performed as the  
15 Secretary may find necessary."

16 (2) Paragraphs (12) and (13) of section 1861(s) of such  
17 Act are redesignated as paragraphs (10) and (11),  
18 respectively.

19 (3) The first sentence of section 1864(a) of such Act is  
20 amended by striking out "the requirements of paragraphs  
21 (10) and (11) of section 1861(s)" and inserting in lieu thereof  
22 "the requirements of section 1861(e)(9), section 1861(j)(15),  
23 or the second sentence of section 1861(s)".

24 (b)(1) Section 1861(e) of such Act is amended—

(A) by striking out “and” after the semicolon at the end of paragraph (8);

(B) by redesignating paragraph (9) as paragraph (10); and

(C) by inserting after paragraph (8) the following new paragraph:

“(9) is licensed under section 371 of the Public Health Service Act with respect to any laboratory (as defined in section 370 of such Act) which is a part of the institution; and”.

(2) Section 1861(j)(15) of such Act is amended by inserting after “physical facilities thereof” the following: “(including a license under section 371 of the Public Health Service Act with respect to any laboratory (as defined in section 370 of such Act) which is a part of the institution)”.

(3)(A) Subparagraphs (C) and (D) of section 1814(a)(2) of such Act are each amended by striking out “and (9)” and inserting in lieu thereof “and (10)”.

(B) Section 1861(f)(2) of such Act is amended by striking out “(3) through (9)” and inserting in lieu thereof “(3) through (10)”.

(C) Section 1861(g)(2) of such Act is amended by striking out “(3) through (9)” and inserting in lieu thereof “(3) through (10)”.

1       (4)(A) Section 1865(a)(3) of the Social Security Act is  
2 amended by striking out "paragraph (6) thereof" and insert-  
3 ing in lieu thereof "paragraphs (6) and (9) thereof".

4       (B) Section 1865(a)(4) of such Act is amended by strik-  
5 ing out "paragraph (9) thereof" and inserting in lieu thereof  
6 "paragraph (10) thereof".

7       (C) The third sentence of section 1865(a) of such Act is  
8 amended by inserting "(other than those in subsections (e)(9)  
9 or (j)(15) thereof)" after "section 1861 (e), (j), or (o),".

10       (c) Section 1866(e) of such Act is amended by inserting  
11 ", independent clinical laboratory," after "rehabilitation  
12 agency".

13       (d) The amendments made by this section shall become  
14 effective three years after the date of the enactment of this  
15 Act.

16               PAYMENT TO PHYSICIANS WITH RESPECT TO

17                       LABORATORY TESTS

18       SEC. 6. (a) Section 1842 of the Social Security Act is  
19 amended by inserting at the end the following new subsec-  
20 tion:

21       "(h) If a physician's bill or request for payment for a  
22 physician's services includes a charge to a patient for a labo-  
23 ratory test for which payment may be made under this part,  
24 the amount payable with respect to the test shall be deter-  
25 mined as follows:



1           “(1) If the bill or request for payment indicates  
2           that the physician who submitted the bill or for whose  
3           services the request for payment was made personally  
4           performed or supervised the performance of the test or  
5           that another physician with whom that physician  
6           shares his practice personally performed or supervised  
7           the test, the payment shall be based on the reasonable  
8           charge for the test (less the applicable deductible and  
9           coinsurance amounts).

10           “(2) If the bill or request for payment indicates  
11           that the test was performed by a laboratory, identifies  
12           the laboratory, and indicates the amount the laboratory  
13           charged the physician who submitted the bill or for  
14           whose services the request for payment was made,  
15           payment for the test shall be based on the lower of—

16                   “(A) the laboratory’s reasonable charge to  
17                   individuals enrolled under this part for the test, or

18                   “(B) the amount the laboratory charged the  
19                   physician for the test,

20           plus a nominal fee (where the physician bills for such a  
21           service) to cover the physician’s costs in collecting and  
22           handling the sample on which the test was performed  
23           (less the applicable deductible and coinsurance  
24           amounts).

1           “(3) If the bill or request for payment indicates  
2           the test was performed by a laboratory and identifies  
3           the performing laboratory but does not include the  
4           amount charged by that laboratory, payment shall be  
5           the lowest charge at which the carrier determines the  
6           test could have been secured by a physician from a  
7           laboratory serving the locality based on available data  
8           including charge schedules of laboratory prices to phy-  
9           sicians (less the applicable deductible and coinsurance  
10          amounts).

11          “(4) If the bill or request for payment (A) does  
12          not indicate who performed the test, or (B) indicates  
13          that the test was performed by a laboratory but does  
14          not identify the laboratory, payment may not be made  
15          under this part.”.

16          (b) Section 1124(a)(1) of the Social Security Act is  
17          amended by inserting before the period at the end the follow-  
18          ing: “, and in the case of a disclosing entity which is an  
19          independent clinical laboratory, furnish such information and  
20          access to its records as the Secretary may require to deter-  
21          mine whether and in what amounts the laboratory has  
22          charged a physician for laboratory services performed by the  
23          laboratory”.

24          (c) The amendments made by this section shall apply to  
25          bills submitted and requests for payment made on or after

1 such date (not later than July 1, 1979) as the Secretary of  
2 Health, Education, and Welfare prescribes by a notice pub-  
3 lished in the Federal Register.

4 HOSPITAL-ASSOCIATED PHYSICIANS

5 SEC. 7. (a)(1) Section 1861(q) of the Social Security Act  
6 is amended by adding "(1)" after "(q)" and by adding before  
7 the period at the end thereof the following: "; except that the  
8 term does not include any service that a physician may per-  
9 form as an educator, an executive, or a researcher; or any  
10 professional patient care service unless the service (A) is per-  
11 sonally performed by or personally directed by a physician for  
12 the benefit of the patient, and (B) is of such nature that its  
13 performance by a physician is appropriate."

14 (2) Section 1861(q) is amended by adding the following  
15 paragraph at the end thereof:

16 "(2) Pathology services shall be considered 'physicians'  
17 services' to patients only where the physician personally per-  
18 forms acts or makes decisions with respect to a patient's di-  
19 agnosis or treatment which require the exercise of medical  
20 judgment. These include operating room and clinical consul-  
21 tations, the required interpretation of the significance of any  
22 material or data derived from a human being, the aspiration  
23 or removal of marrow or other materials, and the administra-  
24 tion of test materials or isotopes. Such professional services  
25 shall not include professional services such as the perform-

1   ance of autopsies, and services performed in carrying out re-  
2   sponsibilities for supervision, quality control, and for various  
3   other aspects of a clinical laboratory's operations that may  
4   appropriately be performed by nonphysician personnel.”.

5       (3) Section 1861(b) of such Act is amended—

6           (A) by striking out “or” at the end of paragraph

7       (6),

8           (B) by striking out the period at the end of para-  
9       graph (7) and inserting “; or”, and

10          (C) by adding at the end thereof the following  
11       paragraph:

12           “(8) a physician, if the services provided are not  
13       physicians' services (within the meaning of subsection  
14       (q)).”.

15       (b)(1) Section 1861(s) of the Social Security Act is  
16   amended by adding at the end thereof: “The term ‘medical  
17   and other health services’ shall not include services described  
18   in paragraphs (2)(A) and (3) if furnished to inpatients of a  
19   provider of services unless the Secretary finds that, because  
20   of the size of the hospital and the part-time nature of the  
21   services or for some other reason acceptable to him, it would  
22   be less efficient to have the services furnished by the hospital  
23   (or by others under arrangement with them made by the hos-  
24   pital) than to have them furnished by another party.”.

1       (2) Section 1842(b)(3) of such Act is amended by adding  
2 at the end thereof the following: "The charge for a physi-  
3 cian's or other person's services and items which are related  
4 to the income or receipts of a hospital or hospital subdivision  
5 shall not be considered in determining his customary charge  
6 to the extent that the charge exceeds an amount equal to the  
7 salary which would reasonably have been paid for the service  
8 (together with any additional costs that would have been in-  
9 curred by the hospital) to the physician performing it if it had  
10 been performed in an employment relationship with the hos-  
11 pital plus the cost of other expenses (including a reasonable  
12 allowance for traveltime and other reasonable types of ex-  
13 pense related to any differences in acceptable methods of or-  
14 ganization for the provision of services) incurred by the phy-  
15 sician, as the Secretary may determine to be appropriate."

16       (c) Section 1861(v) of the Social Security Act is amend-  
17 ed by adding at the end thereof the following new paragraph:

18       "(8)(A) Where services are furnished by a physician  
19 under an arrangement (including an arrangement under  
20 which the physician performing the services is compensated  
21 on a basis related to the amount of the income or receipts of  
22 the hospital or any department or other subdivision) with a  
23 hospital or medical school, the amount included in any pay-  
24 ment to the hospital under this title as the reasonable cost of  
25 the services (as furnished under the arrangement) shall not

1 exceed an amount equal to the salary which would reason-  
2 ably have been paid for the services (together with any addi-  
3 tional costs that would have been incurred by the hospital) to  
4 the physician performing them if they had been performed in  
5 an employment relationship with the hospital (rather than  
6 under such arrangement) plus the cost of other expenses (in-  
7 cluding a reasonable allowance for traveltime and other rea-  
8 sonable types of expense related to any differences in accept-  
9 able methods of organization for the provision of the services)  
10 incurred by the physician, as the Secretary may determine to  
11 be appropriate.”.

12 (d)(1) Section 1833(a)(1)(B) of the Social Security Act is  
13 amended by inserting “(except as provided in subsection (i))”  
14 immediately after “amounts paid shall”.

15 (2) Section 1833(b)(2) of such Act is amended by insert-  
16 ing “(except as otherwise provided in subsection (i))” immedi-  
17 ately after “amount paid shall”.

18 (3) Section 1833 of such Act is amended by redesignat-  
19 ing the second subsection (g) as subsection (h) and by adding  
20 at the end thereof the following:

21 “(i) The provisions of subsection (a)(1)(B) and clause (2)  
22 of the first sentence of subsection (b) shall not apply to any  
23 physician unless he has entered into an agreement with the  
24 Secretary under which he agrees to be compensated for all

1 such services on the basis of an assignment the terms of  
2 which are described in section 1842(b)(3)(B)(ii).”.

3 (e) The amendments made by this section shall, except  
4 those made by subsection (d), apply to services furnished in  
5 accounting periods of the hospital which begin after the  
6 month following the month of enactment of this Act. The  
7 amendment made by subsection (d) shall become effective on  
8 July 1, 1979.

Senator KENNEDY. I have had a chance to review the administration's testimony on clinical labs before the hearing. I believe that some valid issues are raised and that the legislation can be amended to accommodate the Administration's legitimate concerns.

Senator Schweiker?

Senator SCHWEIKER. Thank you, Mr. Chairman.

I am pleased to join with you, Senator Kennedy, and with Senator Javits this morning for our hearing on three vital pieces of legislation, the health planning amendments, nurse training, and Clinical Laboratories Improvement Act.

The Nurse Training Amendments of 1979 would continue funding for both nurse training programs and nursing students. I have some concerns about the President's veto of the Nurse Training Amendments of 1978 and the administration's expressed intent to abolish all funding for nurse training programs for the support of nursing students.

Nursing is a vital component of this system. It has an expanding role to play in health education, disease prevention, and health care. Although the overall supply and demand for nursing may be in balance, there are obvious shortages of nurses in many geographical areas and certain types of hospitals.

In addition, numerous developments and improvements are needed in undergraduate nurse education and advanced nurse training, and the accomplishment of these goals will require Federal support.

The legislation under consideration will authorize nurse training programs and student assistant support through fiscal year 1980. This will enable the Congress to consider the future direction of all health manpower programs at one time as new health professionals educational assistance legislation is prepared for 1981.

Finally, the present bill includes a request of the National Academy of Science for a study of nurse training that will help clarify the Nation's nursing needs as well as the best methods to satisfy those needs.

The health planning amendments represent a thorough and a bipartisan effort to strengthen the health planning system's ability to manage its resources. This bill is similar to the one which passed the Senate last year with two modifications regarding certificate-of-need requirements—bringing HMO's on an equal footing with other similar organizations and including physicians office equipment in excess of \$150,000 only if it is used regularly for inpatients.

I believe these changes strengthen the amendments and will make the bill more widely acceptable. Building upon existing law, the planning amendments reinforce the role of the State in controlling the planning process at the same time it provides for congruity with local health planning decisions by tying certificate-of-need decisions to the health plan.

In addition, there are positive incentives in the bill to encourage hospitals to discontinue unneeded beds or services.

I fully support the bill's attempt to correct some of the glaring problems with the current system while augmenting decisionmaking authority at the local level where it can be given an opportunity to work.



Finally, we will be discussing this morning the Clinical Laboratory Improvement Act of 1979 introduced by Senator Javits. I understand many significant changes have been made in this year's version of the bill which seek to integrate the proposed new authority with laboratory regulations currently in place.

I hope those who testify will address the scope and regulatory nature of this bill.

Thank you, Mr. Chairman.

Senator KENNEDY. Senator Javits?

Senator JAVITS. Thank you very much, Mr. Chairman.

Mr. Chairman, first let me express my great pleasure with respect to the position of Senator Schweiker. He has taken a very strong and leading position with respect to these matters and comes very well equipped. I must say I have derived great satisfaction from this work which I knew he could do.

As for the Health Planning Amendments of 1979, I think my colleagues fully covered those in their views. I would like to point out that my own State has long been a pioneer in this field. It has worked out extremely well for us, especially in the certificate-of-need aspects of the law which enabled us to close down many beds which proved to be unnecessary, or to divert them for necessary use. In view of this tremendous inflation—or double rate of inflation—our normal standard is bad enough. But it seems to me that this becomes a critical element of the national health plan and will greatly assist us as we move toward universal coverage.

In some way, we may differ as to the way in which it should be done, but we certainly do not differ—even with private enterprise—in the fact that everyone should be covered.

I would also like to call attention to that section of the bill which deals with helping improve hospitals in order to meet life and safety codes and necessary accreditation standards such as those contained in this bill.

As to nurses training, Mr. Chairman, this has been a long standing concern and care of mine. My interest was intensified by a marvelous woman named Frances Bolt, herself a nurse, who served with me in the House and was, as it were, the prime advocate of the nurses corps.

I think Senator Kennedy was extremely accurate in saying that the statisticians and the experts tell us there is no shortage, and they do not think there is going to be; yet everybody is looking for nurses and cannot find them. Something is wrong somewhere.

Because of my long standing interest in the nursing education I introduced this 1-year carryover bill and have joined my colleagues in trying to prevent the President's pocket veto from detaining the advancing effort to supply our country adequately with well trained nurses.

Finally, regarding the Clinical Laboratory Improvement Act of 1979, this committee passed the 1967 bill which had a very fine effect, although the coverage is not broad enough. It covers roughly 1,000 laboratories as opposed to the 14,000 that should be included.

It has passed the Senate on a number of occasions. It has had problems with the House because of both scheduling and members delaying it for ideological reasons, blocking it at a time when the

session was expiring; a few determined members can block anything.

Mr. Chairman, I hope we do not wait until some horrendous outbreak is caused by faulty analysis in these laboratories or when they are hit with some fantastic scandal. We have already had kickback scandals, and we seem to be just waiting for the bomb to burst in this matter.

Also, I think the provisions with respect to the way in which pathologists should be compensated is a very intelligent and sound one. It deals with a very deep fault in the system in which the public is not being properly used.

Proliferation of testing is flagrant. Great dependence is now placed on testing as witnessed, for example, by advanced tests which are favored by the Blue Cross/Blue Shield.

This area very urgently needs correction. I welcome the fact that we are investigating this in a detailed way.

I appreciate the critical analysis, and it will give us a better bill or a better way to deal with it.

I welcome our witnesses very much. I will apply myself to their views, and I am very pleased that all my colleagues will, and I think it is true of all the cosponsors. On this bill, there were eight other Senators including myself, Senator Kennedy and Senator Williams, the chairman of our committee, and Senators Randolph and Riegle, all members of this committee, and other Senators.

So, Mr. Chairman, I would like to thank you very much for calling this hearing so early in the session, and giving us all an opportunity to deal with these three very critical problems in our health system. I look forward to being able to act upon them early so that we do not get delayed at the end of the session when almost anything can be blocked.

Thank you very much.

[The prepared statement of Senator Javits follows:]

#### PREPARED STATEMENT OF SENATOR JACOB K. JAVITS

Mr. Chairman, I am pleased to join you today to receive testimony from the Administration and interested organizations on the Health Planning Amendments of 1979, the Nurse Training Act of 1979, and the Clinical Laboratory Improvement Act of 1979.

#### S. 544, THE HEALTH PLANNING AMENDMENTS OF 1979

S. 544, the Health Planning Amendments of 1979, is a bill which extends the provisions of the Health Planning and Resources Development Act for three years and makes a number of changes which I believe will do much to improve the health planning process.

My own State of New York has long been a pioneer and leader in the field of health planning. New York enacted the first certificate-of-need law in 1966; that law has been instrumental in keeping the growth in capital expenditures for unneeded beds and facilities to a minimum. Since the adoption of the State's CON law, 64,000 beds have been disapproved in the CON process. The estimated savings associated with these disapprovals is \$2 billion in capital costs, one million more each year in operating expenses, and untold millions which would have resulted from patient charges for unneeded services.

Savings linked to planning coupled with the State's aggressive hospital cost control program has transformed New York from the state with the highest rate of inflation for hospital services to a state with one of the lowest rates of inflation. In 1970, the inflation rate was 14.7; by 1976, this rate had dropped to 8.7 percent.

Planning efforts in New York State have also led to the closure of more than 6,000 unneeded and in some cases substandard beds since 1975. During the same

period, more than 1,000 acute care hospital beds have been converted to needed and more appropriate use.

In summary, the New York experience clearly demonstrates that a strong planning system can effectively curb growth in services, capital expenditures, and overall costs.

With respect to S. 544, I believe many of the amendments contained therein will serve to further strengthen the planning process. Some of the proposed amendments would accomplish the following:

Assure that the role of HEW in developing national guidelines is restricted to offering guidance and suggestions, and does not permit mandating the outcome of a local planning process.

Strengthen the role of States' Governors in the planning process.

Assure that States' certificate-of-need decisions are made consistent with the plans developed by the local and State planning agencies.

Promote increased and more effective participation of consumer planning board members by providing technical assistance and staff resources to these members as well as providing added liability protection from groundless suits.

Assure that state certificate-of-need programs do not discriminate against health maintenance organizations.

Better integrate the planning processes for mental health, alcohol and drug abuse programs with the overall health planning process.

In addition to these important amendments, the bill also contains a provision which provides grants to States to support the voluntary closure, conversion or merger of unneeded services and facilities. I am particularly interested in this provision since New York is undertaking many initiatives along these lines.

I have also had a long-standing interest in Sec. 1625. This provision permits the Secretary of HEW to make grants to public general hospitals for the purpose of making physical improvements in order to meet life/safety codes and accreditation standards. While I recognize that we are in a period of contraction in the area of health facilities, I believe it is imperative to recognize the important role that public hospitals play in our health care system. For those facilities destined to remain open, we must assure that such facilities are safe and capable of providing the highest quality of health services.

#### S. 230, THE NURSE TRAINING AMENDMENTS OF 1979

The question of whether to continue federal support to nurse training programs has received considerable attention in the Congress in recent weeks. Only a short time ago, this subcommittee met to review the President's proposed Fiscal Year 1980 health budget. During that hearing, Administration officials and representatives from the nursing profession offered conflicting views on the need for the continuation of nurse training programs. In my judgment, data presented during that hearing failed adequately to support the Administration's position on this issue and left questions such as the following unanswered:

What will the impact be on the nursing schools and nursing students when funds under this Act are suddenly eliminated?

In the absence of federal support, what is the outlook for sustaining the graduation of adequately trained nurses?

How will reductions in funds for institutional support and student assistance affect minority enrollment?

With respect to student assistance programs available through the Office of Education, are sufficient funds available in these programs to offset the demand which will certainly occur when funds under the Nurse Training Act are eliminated?

How will the need for nurses change with the implementation of national health insurance or increases in HMOs, community health centers and other forms of ambulatory care centers?

Thus far, the Administration has been unable to provide the Congress with studies or other evidence which answers these and other questions. A study conducted by the Congressional Budget Office in May, 1978—perhaps the most objective study currently available—found the following:

"Assessments of the adequacy of the supply of nurses depend on somewhat subjective estimates of 'need' and uncertain predictions of the number of nurses in training and of the proportion of trained nurses that practice nursing. Nevertheless, the current aggregate supply of nurses appears adequate and, if current trends continue, supply should exceed or roughly equal demand in the future."

The question which arises in connection with this statement is: Can current trends continue without federal support? The CBO report also stated:

"\* \* \* current trends may not continue and, if changes in demand occur, they will alter slightly the adequacy of the supply of nurses . . . Demand for nurses, particularly in ambulatory care settings, may increase if a comprehensive national health insurance program is implemented or if the roles of nurses are expanded. The geographic distribution of nurses remains uneven . . . The impact of possible nurse shortages on the quality of health care is uncertain, but in shortage areas, nurses with less training are more heavily utilized and many jobs for nurses with more advanced training remain unfilled.

"The adequacy of the supply of graduate degree nurses is very uncertain, but most subjective assessments report that fewer nurses with advanced degrees are available than are desired."

It is my hope that today's hearing will provide us with new information which satisfactorily resolves these issues.

#### S. 590, THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979

Mr. Chairman, the Clinical Laboratory Improvement Act, of which I am the author, was introduced on March 8 of this year, co-sponsored by Senators Kennedy, Williams, Randolph, Stafford, Reigle, Inouye, Metzenbaum, and Bellmon. This bill has twice passed the Senate, but was not voted upon in the House of Representatives due to scheduling delays.

I first became committed to achieving these necessary reforms more than a decade ago. Since then, efforts to control the abuses under existing authority have been ineffectual. As medical science becomes more dependent on lab tests for both diagnosis and prevention, the need for this measure grows even greater.

Laboratory tests are basic to quality of care. Yet according to HEW estimates, there is an error rate of 8 to 25 percent nationwide for clinical laboratory performance, depending upon the specialty tested. That means that over 2 million—out of 12 million—laboratory results are in error every day, resulting in a higher rate of unnecessary hospitalization, unneeded surgery, inappropriate treatment, undiscovered disease, injury, and even death.

Yet, a lack of administrative commitment and direction persists, hampering the effort to improve laboratory performance in the field. In comparison with last year's bill, which passed the Senate by unanimous consent, this bill rationalizes and simplifies the existing patchwork of overlapping, confusing, and incomplete jurisdictional arrangements without creating a new Federal bureaucracy. Instead, the program is carefully integrated into the existing program of medicare certification that already applies to a majority of large laboratories and which is staffed and administered by State personnel in every State. States would be fully reimbursed for their enforcement expenses through the usual medicare agreements with the Secretary of Health, Education, and Welfare.

The important function of the Center for Disease Control is preserved through its responsibility to develop the national standards, to provide technical assistance, and to monitor the adequacy of State enforcement.

Problems of fraud and abuse in laboratories also persist. On September 26, 1978, The Wall Street Journal carried the headline, "Laboratory Kickbacks to Doctors Persist Despite Federal and State Investigations," and called the problem a "chronic ailment."

It is estimated that up to 33% of laboratory costs in some parts of the country can be attributed to fraud and inappropriate cost. The Congressional Budget Office anticipates that this bill will effect a savings of 10% overall. Thus the reforms this bill will provide will save taxpayers and the government substantial amounts of money.

To continue to tolerate poor laboratory practices and abuses is unconscionable. I believe the American health consumer deserves a higher level of performance, which I believe would be assured under the licensure and improvement programs provided in this bill which will apply to the major clinical laboratories involved in health care delivery.

Senator SCHWEIKER. Mr. Chairman, I have here a statement by Senator Hatch for inclusion in the record.

Senator KENNEDY. It will be included in the record at this point.  
[The prepared statement of Senator Hatch follows:]



## PREPARED STATEMENT OF SENATOR ORRIN G. HATCH

NURSE TRAINING ACT, S. 230; CLINICAL LABS, BILL, S. 590; AND HEALTH PLANNING ACT, S. 544

When Secretary Califano testified before this Subcommittee on the 26th of January, making his case for the Administration's 1980 health budget, he said at least one thing with which I can agree, and he said it very well. He said that any ensuing budgetary debate in which we on this committee engage ourselves, is not a debate between the friends of better health care on the one hand, and its enemies on the other. That is, that the debate about specific health care programs and this Subcommittee's budgetary priorities is a debate about means, not ends.

The stated and most immediate object of the Nurse Training Act about which testimony will be heard today, for example, is to reverse the shortage of professional nurses which directly compromises the quality of health care in lower income areas and in the smaller states. While there is a debate among informed and reasonable people over whether or not there really is a national shortage of nurses, I believe that everyone can at least agree to the prevailing mal-distribution of professional nurses which is having such a painful impact on states like my own.

I say this as a prologue to some questions I have about the legislation, questions which can hopefully be answered at today's hearing. For example, just taking this question of mal-distribution, the presently re-written bill includes a provision which on the face of it is laudatory, and I am specifically referring to Section 201. That is, the Secretary will be permitted to raise the annual limit of federally insured loans to medical students if the Secretary "determines that the costs of education at such schools requires such increases."

I would like to know what factors will influence the Secretary's final decision? Has a formula already been determined, or will he be using a pre-existing means of allocating increases? In order to assure that money is better distributed, since we all agree to the current funding inequity, does this mean that the Secretary will also be subtracting from the loan grants to institutions which are already receiving too much of a federal allotment?

These are just preliminary questions I hope we will all keep in mind against the backdrop of today's hearing. These and others I ask, and respectfully solicit the support of our chairman, Senator Kennedy; Senator Schweiker; and my other distinguished colleagues in assuring that there are none of the proverbial "open ends" to this legislation before it or any other bill subject to today's hearings are reported to the full Committee.

QUESTIONS CONCERNING THE NURSE TRAINING ACT (S. 230) AND S. 544

(1) Would you please explain how the "financial distress grants" provided in Section 205 of the bill will work? That is, what criteria would be used to determine whether individual institutions do or do not deserve such "grants," and how do you envision its impact on those predominantly black medical schools which are currently facing serious financial troubles?

(BACKGROUND NOTE.—Sec. 205 provides for the Secretary-HEW to give so-called distress grants to medical schools facing serious trouble or shutdown, however, the section is ambiguous about how these grants will be given, how much, what limits on them if any, or any other instructions re: guidelines.)

(2) How much money would Section 203 save us? That is, I am assuming that by eliminating the mandatory participation of every medical and osteopathic school in some kind of practitioner-training program, that money will be saved without jeopardizing the desired total result of practitioner-training nationally? Am I correct in believing this?

(BACKGROUND NOTE.—Sec. 203 changes the existing public health service act so that if one school in a designated geographic area provides for a medical or osteopathic training program, every other school in that area will no longer be forced to run the identical program. By pooling resources, it appears that this would be a substantial cost saving. The purpose of the above question is really to get this on the record.)

(3) Concerning the study proposed in section 112 of the bill, what happens if the Institute of Medicine turns down the bill's proposal for a study on nursing shortages? That is, who specifically would HEW turn towards conducting the study? Is there a copy of a study model available, an outline of what questions will be asked? I ask all of this in order to assure that such a study will be optimally verifiable, and so lend itself to greater public credibility once its results are issued. Can you comment on this?

Senator KENNEDY. We welcome an old friend, Julie Richmond, who is the Assistant Secretary for Health and the Surgeon General of the United States, and your distinguished colleagues.

We will hear from the Surgeon General and the Assistant Secretary. I would ask him to summarize it, if he would, and then we will hear the testimony on the nurse training legislation and finally on clinical labs.

Senator Javits has other important meetings and wants to be here during the testimony of those particular witnesses, and then we will come back to the planning panel as our final group of witnesses.

So we welcome you, Dr. Richmond, and your associates.

**STATEMENT OF JULIUS B. RICHMOND, M.D., ASSISTANT SECRETARY FOR HEALTH AND SURGEON GENERAL, ACCOMPANIED BY HENRY FOLEY, PH. D., ADMINISTRATOR, HEALTH RESOURCES ADMINISTRATION; MARTIN BAUM, PH. D., SPECIAL ASSISTANT TO THE DEPUTY ASSISTANT SECRETARY FOR HEALTH (PLANNING AND EVALUATION); EDWARD KELLY, DEPUTY DIRECTOR, BUREAU OF HEALTH STANDARDS AND QUALITY, HEALTH CARE FINANCING ADMINISTRATION; CAROL EMMOTT, PH. D., SPECIAL ASSISTANT, OFFICE OF THE DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH)**

Dr. RICHMOND. Thank you very much, Mr. Chairman. It is a real pleasure to, again, appear before the members of this subcommittee and before you. Before getting into the testimony, I would like to express our appreciation for the deep understanding and commitment which the members of the committee, both majority and minority, have for the issues which we are discussing today and the wise counsel which they have given to members of the Public Health Service as we have worked on these issues.

I think the introductory comments of the member of this subcommittee are reflections of the considerable knowledge and skill that the members have in these areas.

The health planning and nurse training authorities are administered in the Health Resources Administration of the Public Health Service, and accordingly, I am accompanied by Dr. Henry Foley, the Administrator of the Health Resources Administration, on my right.

The clinical laboratory program is cooperatively administered by the Public Health Service and the Health Care Financing Administration. Dr. Martin Baum of the Public Health Service Clinical Laboratory Task Force and Mr. Edward Kelly, the Deputy Director of the Health Standards and Quality Bureau will be able to respond to any question you may have in these areas, and I am also accompanied by Dr. Carol Emmott of our legislative staff.

I will endeavor, as you suggested, Mr. Chairman, in the light of the heavy schedule that you have for this morning's session, to be as brief as I possibly can.

For the first time in the area of planning, the Nation has a process that is well on its way to addressing critical health system deficiencies such as the inflationary costs of health care, which have already been commented on, the unequal access to health

care, particularly for minorities and the disadvantaged, the maldistribution of health care facilities and manpower, the lack of consumer participation in the decisionmaking process and fragmentation that separates local, State, and Federal activities in both the public and private sectors.

We have only just begun to realize the potentialities of this program, and I would emphasize, Mr. Chairman, that those critics of the program who expect instant successes are often unaware of the tremendous complexity of this process of health planning. And I think it is also important to note that as a Nation we are still relatively early in this process, but as Dr. Foley and members of your subcommittee have already indicated, there have been significant achievements.

I will submit a summary of significant program accomplishments for the record. Briefly, I would like to highlight our proposals and provide brief remarks on your legislation.

Among provisions in our proposed legislation, we aim at the following. First, cost restraint. A number of our proposed revisions in the planning legislation, in addition to hospital cost containment and forthcoming proposed capital limit suggestions, will be aimed at restraining the inflationary increases in health care costs.

Our bill will authorize a 3-year demonstration grant to promote the closure, conversion or decertification of unneeded hospital services and beds. Our proposed authorization of appropriations will be \$30 million for fiscal year 1980 and such sums as may be necessary for the following 2 fiscal years. This closure and conversion program will provide financial incentives and technical assistance to hospitals to discontinue inpatient hospital services or to convert them to fill local unmet needs.

We would also propose to strengthen the health planning program's ability to influence the health care system. We will again propose to close a loophole in the State certificate-of-need program. Having learned from the well publicized CAT scanner experience, we believe it is important to cover all acquisitions of costly medical equipment, under certificate-of-need, no matter where the equipment is to be located.

The widespread development of health maintenance organizations is one way of controlling the rate of inflation in health care costs. Our proposal would require State and local planning agencies to apply the same criteria to health maintenance organizations as are applied to other health entities but would authorize the department to establish other criteria, if necessary, to enhance HMO development.

Second, concerning State role, our bill will propose several changes designed to enhance and strengthen the role of States and Governors in the implementation and operation of the health planning program. To give the State health plan greater visibility, sanction and public support, our bill will allow the Governor to approve or modify that plan after it has been developed and revised by the SHPDA and the SHCC.

In addition, our bill would require that certificate-of-need decisions be consistent with the State health plan. It would also permit the Governor to appoint the chairperson of the State health coordinating council. Also, we will propose that a Governor be given

greater latitude in requesting redesignation of existing health service areas within the State. Our bill will also permit changing the boundary of the health service area if another boundary would be more suitable for planning purposes.

Concerning program effectiveness, we will also propose a number of changes intended to enhance the effectiveness of the program and the performance of State and local health planning agencies. Our bill, will provide for the review and revision of health systems plans and State health plans every 3 years. Our bill will also propose greater flexibility in funding health systems agencies by replacing the current per capita and minimum grant funding mechanisms with discretion for the Secretary to set funding levels. This authority is necessary, we believe, to permit a phase-in funding and to encourage innovative advances in local planning. The related change we are proposing would permit returning to conditional status, for not more than 24 months, any fully designated HSA or SHPDA if it failed to continue to meet all the applicable requirements for full designation or poorly performed its mandated function.

In addition to these proposed changes, there will be several other major changes in our bill. We will, again, propose to expand the authority of a public regional planning body or unit of general purpose local government that also serves as an HSA.

We also propose two significant changes regarding Federal sanctions with respect to inadequate State planning programs. By this summer, most SHPDA's will have reached the limit on their conditional designation with, I am disappointed to say, few State certificate-of-need programs being in place. The Secretary recognizes that there might be circumstances in which the certificate-of-need program would be delayed despite reasonable efforts. Therefore, we will propose discretion to extend the conditional status of SHPDA's beyond 36 months if it is determined that both the agency and the State are making a good-faith effort toward enacting an acceptable certificate-of-need program.

The law further requires that, if a State does not have a fully designated SHPDA by September 30, 1980, the Secretary must withhold assistance under the Public Health Service Act and related laws. Our experience with other programs has shown that such a severe penalty is not practicable. We propose, as a more appropriate penalty, the reduction of the State's formula grant under the Public Health Service Act by 25 percent during the first year of violation, 50 percent during the second year, 75 percent during the third year, and 100 percent during the fourth year of violation.

Finally, we would not seek extension of the facilities construction authority. We feel they are counterproductive to our goal of holding down capital expenditures. At a time when the bulk of the evidence clearly points to an excess capacity of 130,000 beds and where future investments should decline, it makes little sense for the Federal Government to be subsidizing future growth. Nationally, however, we will administer the continuing responsibilities of institutions which have received support under title 16 such as the uncompensated care, community service, and postconstruction loan-monitoring activity.



If I may, Mr. Chairman, I would like to briefly comment on a few of the major provisions in your bill, S. 544. In many instances, we support your revisions for the planning program and are introducing similar amendments of our own, as I have already discussed.

Specifically, we would agree with expanding the authority of the governing board in a public health systems agency, easing redesignation requirements especially for interstate HSA's, returning fully designated HSA's and SHPDA's to conditional status if they fail to perform satisfactorily, permitting more involvement by Governors in the State health plan, easing the requirement that the Secretary withhold funds on September 30, 1980, from States with no satisfactory certificate-of-need program, and requiring coordination between planning agencies and other cost containment entities within the State, especially rate-review commissions.

However, in some cases, we will be proposing a different approach. S. 544 requires that State alcohol abuse, drug abuse, and mental health agencies prepare those portions of the State health plan. While we appreciate the role of those agencies, we also feel that the Governor of each State should have the discretion to decide where those responsibilities should be placed.

S. 544 maintains authorizations for a number of health facilities, construction activities, and developmental funds. We feel that these authorities are counterproductive to our goal of holding down capital expenditures. The Nation needs to reduce, not increase, hospital capacity.

In addition, we would urge, as we did last year, that certificate-of-need cover all acquisition for expensive medical equipment no matter where it is to be located.

And finally, we believe that the \$1.7 billion, 3-year authorization in S. 544 is excessive in the light of the President's commitment to holding down Federal spending.

I would now shift, Mr. Chairman, to discuss with you the proposed legislation to extend Federal nurse training authorities through the fiscal year 1980. For the past 22 years, the Federal Government has provided substantial support for nursing education.

From 1956 through 1978, about \$1.5 billion has been awarded for student traineeships, loans and scholarships, for construction and basic support for nursing education programs and for projects to improve nursing education and recruitment.

With the help of this Federal support, there has been a marked increase in the supply of nurses in recent years. Graduations from nursing education programs have more than doubled since the enactment of the Nurse Training Act of 1964.

In addition, an increased proportion of the nurse population is actively employed in nursing today. Through actions of the private, State and local governmental sectors, combined with higher Federal assistance, we have put in place the capacity to produce an adequate supply of nurses to meet future needs.

The recent Congressional Budget Office and our departmental analyses of nursing supply and demand have concluded that the supply of nurses through 1990 and through 1985 respectively is likely to be sufficient to meet the demands resulting from probable changes in the health care system.

Mr. Chairman, the administration's nurse training bill for 1980 supports a targeted approach to Federal assistance for nurse training. This approach recognizes an aggregate supply of nurses and focuses Federal resources on problems of geographic shortages.

This bill also assures that nursing students will be eligible for financial assistance on the same basis as other health professional students. The draft bill would also authorize appropriations of \$1.743 million for fiscal year 1980 for special projects, including projects to improve the geographic distribution of nurses, to increase the representation of individuals with disadvantaged backgrounds in the nursing profession, to develop innovative nursing techniques, emphasizing primary care and prevention, to enhance clinical skills, to provide continuing educational opportunities and to provide some advanced nurse training.

The administration bill would authorize appropriations of \$13 million for fiscal year 1980 for the training of nurse practitioners who are currently in short supply.

These professionals are trained to provide primary care and preventive care, practicing either in complementary or under certain conditions substitute roles for physicians.

Nurse practitioners have proven to be a cost-effective means of increasing the availability of primary care services, especially to underserved areas where they often locate.

The administration's bill would also expand student assistance opportunities for nursing students. The bill would eliminate the 10-percent limit on National Health Service Corps scholarship support available to health care practitioners other than physicians and dentists.

This program offers scholarships with a definite service commitment and has proven to be the most effective means available for attracting health professionals to underserved areas.

In addition, the bill would broaden the health education assistance loan authority to include nurses in graduate programs and would repeal a restriction on the eligibility of nursing students for national direct student loans.

Mr. Chairman, due to the adequacy of current and projected nursing resources, the limited impact of Federal assistance on increasing the overall supply of nurses, the inability of increased aggregate supply to meet the problems of maldistribution and the President's desire to scrutinize Federal expenditures of marginal effectiveness in his efforts to control unnecessary expansion of the Federal budget, investment in the acceleration of the output of professional nurses no longer competes favorably, it seems to us, with more pressing health priorities.

The administration currently is conducting a major review of its support for health professions training with the aim of developing a new legislative proposal covering various HEW programs affecting health manpower training for fiscal years 1981 and beyond which address the problems particularly of geographic and specialty distribution.

Mr. Chairman, the administration's manpower proposal will take account of the key part played by nurses in the provision of health care in our society. Nevertheless, we believe it is essential to use the necessary extension of nurse training authority to make mid-

course corrections in the evolution of an appropriate Federal role in nursing education.

Congressional consideration of the comprehensive health manpower amendments may not be concluded until the end of this Congress. The need for a redirection of Federal nursing programs as well as the current economic climate and the shared executive and congressional resolve to decrease the Federal deficit lead us to urge the Congress to enact the administration's legislative proposals to provide focus to our nurse training activities.

Now, Mr. Chairman, to shift to present our views on S. 590, the Clinical Laboratory Improvement Act of 1979, and to report on the activities of the Department with respect to the regulation and improvement of clinical laboratories.

Let me assure you that the administration shares your concerns about the need for quality, the prevention of fraud and abuse in the reimbursement of these services, and the containment of costs of clinical laboratory and other health services.

The Department has already initiated steps to accomplish these objectives under current authority. We believe that S. 590 with the changes that we are recommending will permit us to continue the progress made and to achieve our mutual goals.

Even before the introduction of this clinical laboratory legislation the Department attempted to correct many of the problems addressed by the bill, and for the past 2 years, resolution of program differences has been a top priority of the Department.

Working closely with the Administrator of the Health Care Financing Administration under current authorities in the Social Security and Public Health Service Acts, we have made considerable progress despite some impediments in improving the uniformity and effectiveness of our laboratory activity.

For example, the interagency agreement on the regulation and improvement of clinical laboratories that was consummated in 1975 has been updated and improved. Since January 1978, under the agreement, HCFA has been responsible for administering the regulatory functions of both the medicare and the CLIA programs through the medicare provider certification system using State agencies.

The Public Health Service is responsible for the development and promulgation of the scientific and technical standards including personnel requirements for all clinical laboratories covered by the CLIA and medicare programs.

The Public Health Service, through the Center for Disease Control, will also monitor the performance of the State regulatory programs and the several accrediting and approval organizations in the application of these standards.

In addition, the Department is also taking steps to reduce the overlap in inspections between the regulatory program for clinical laboratories and the regulatory program for blood establishments.

Another example of departmental coordination is our task force on clinical laboratories which was established in December 1977. The task force which is comprised of those representatives of those public health service agencies whose programs impact on clinical laboratories and representatives from HCFA provides a depart-

mental forum for the identification, exploration and resolution of problems and issues pertaining to clinical laboratories.

As you know, assuring quality through standards is a primary objective of the Department's clinical laboratory program. In the past, however, there have been differences in the content of the standards and the manner in which these requirements have been applied by the regulatory agencies.

The Department has been working for some time to eliminate these differences and to adopt standards that can be applied uniformly to all federally regulated clinical laboratories.

We believe that all these actions will accomplish the objectives of a well coordinated and uniform regulatory program for clinical laboratories.

We support the basic objectives of S. 590 to create a coordinated authority for the Department's clinical laboratory programs, to establish uniform standards for all clinical laboratories subject to Federal regulations, to eliminate duplication in the administration of the program, and to provide additional authority to deal with cases of fraud and abuse.

Administration support, however, is contingent on certain changes affecting the scope and funding levels of the bill. As you know, we supported similar legislation in the last Congress.

The administration's position, to some extent, has changed because of the success of our administrative actions in bringing about greater coordination and uniformity within the clinical laboratory program as well as our desire to keep unnecessary Federal spending and Federal regulations in check.

We support the bill's concept of licensure that would allow us not only to stop medicare reimbursement to clinical laboratories determined to be of poor quality, but to close down such laboratories so that anyone using them would be protected.

This extension of authority closes a potentially dangerous loophole in current law which permits negligent laboratories previously licensed under CLIA 1967 or certified by medicare to continue to provide services despite regulatory action which either prohibits operation in interstate commerce or participation in medicare.

The bill, however, would expand Federal jurisdiction and authority to cover all State and local government owned and operated laboratories. In general, the Department resists the imposition of requirements on State and local institutions unless the need is very clearly indicated.

We do not believe the extension of Federal authority to the approximately 500 laboratories which do not already participate in medicare is warranted. Furthermore, such laboratories are directly accountable to the public via the normal governmental authorizing and budgeting processes.

S. 590 allows the Secretary the latitude to exempt physicians and other health practitioners in group practices of less than six who perform routine tests or procedures only for their own patients.

We believe that this latitude should be extended to include group practices of six or more and to offices where the practitioners do not perform the tests themselves.

The scope and nature of deficiencies in this area are not as yet sufficiently known. For this reason, we would prefer that this



legislation provide for a study of all practitioners offices as proposed in the House bill as reported in the last Congress.

With the authority granted by such a provision, we can collect the necessary data to provide Congress with information that is critical to the development of sound policy in this area.

We appreciate elimination of the requirement for the establishment of an Office of Clinical Laboratories which would greatly, we feel, limit the flexibility of the Secretary to manage the Department most effectively.

However, we believe the administrative provisions in the bill are unnecessary because of the improvement, clarification and smooth functioning of our interagency agreement. Not only would this requirement create an unnecessary bureaucratic layer but it would have detrimental effect, we believe, on policy development.

Mr. Chairman, I will now turn to the two important provisions of the bill that seek to reform medicare reimbursement for laboratory services. As you know, one of the most troublesome and costly abuses that we find in medicare reimbursement for laboratory services is the practice of some physicians who add to their bills substantial markups for services performed by an outside laboratory.

We strongly support the bill's intent to stem this abuse. We are concerned, however, about the potential impact of these provisions on physicians' decisions to accept assignment on beneficiary's out-of-pocket costs.

In addition, we oppose mandating these specific provisions because we are concerned that they limit our authority to adopt other reimbursement options for laboratory services.

We would like to work with the Congress in an effort to develop a more comprehensive approach through both regulation and legislation which would not only curb physician markups for independent laboratory services.

Mr. Chairman, the second set of medicare reimbursement provisions concerns the method by which medicare reimburses hospital associated physicians. We support the objectives of these provisions but believe that sufficient statutory authority currently exists to deal with most of these problems.

We believe that we can work together with the Congress to assure that Federal programs do not bear any excessive costs associated with reimbursement of these physicians.

In summary, Mr. Chairman, the Department concurs in the need for a well coordinated effort to assure the public that clinical laboratory services are accurate and are of the highest quality.

Senate leadership in pursuit of this goal has paralleled a record of recent administrative accomplishments. We hope this progress meets with your approval and would welcome the opportunity to work with the committee to fashion legislation that provides for a limited extension of regulatory authorities, enhances program coordination and aids our efforts to curb fraud and abuse.

Thank you very much, Mr. Chairman. My colleagues and I would be happy to answer questions.

Senator KENNEDY. Thank you very much, Dr. Richmond. Your statement will be printed in its entirety.

[The full text of Dr. Richmond's prepared statement follows:]



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

BY

JULIUS B. RICHMOND, M.D.

ASSISTANT SECRETARY FOR HEALTH

AND SURGEON GENERAL

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

FRIDAY, MARCH 16, 1979

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to be here today and have the opportunity to present our views on three very important legislative issues: Health Planning and Nurse Training, and Clinical Laboratory Improvement.

The health planning and nurse training authorities are administered in the Health Resources Administration of the Public Health Service. Accordingly, I am accompanied by Dr. Henry A. Foley, Administrator, Health Resources Administration. The Clinical Laboratory program is cooperatively administered by the Public Health Service and the Health Care Financing Administration. Dr. Martin Baum of the PHS Clinical Laboratory Task Force, and Mr. Edward Kelly, Deputy Director of the Health Standards and Quality Bureau, will be able to respond to any questions you may have in this area.

- 2 -

I would like to begin by discussing extension of our National Health Planning and Resources Development authorities under Titles XV and XVI of the Public Health Service Act. Renewal of this legislation is critical to meeting our health objectives and is urgently needed. We appreciate your early consideration of this vital legislation.

Back in the early 1970s, it became clear that the fragmentation of responsibility and haphazard allocation of health care resources were problems that would require a new, innovative approach. Congress responded to that need by enacting the National Health Planning and Resources Development Act of 1974. This program seeks to ensure broad public participation in the development of a comprehensive policy regarding health services, manpower, and facilities. Now, for the first time, the Nation has a mechanism that is well on its way to addressing critical health system deficiencies such as:

- . Runaway and inflationary costs of health care;
- . Unequal access to health care, especially for minorities and the disadvantaged;



- 3 -

- . Maldistribution of health care facilities and manpower;
- . Lack of consumer participation in the decision-making process; and
- . Fragmentation that separates local, State and Federal activities in both the public and private sectors.

Extension and strengthening of the National Health Planning program is part of the Administration's overall strategy for controlling the excessive increases in health care costs. The Administration has already introduced its hospital cost containment proposal which is the key element in this strategy and one of the President's highest priorities. Coupled with the health planning and hospital cost containment legislation, we will also be submitting in the near future legislation that would place an annual national cap on hospital capital expenditures. This legislation will also set and enforce mandatory guidelines for approved hospital construction. These capital limit proposals are essential to a fully effective health planning system and will provide an important adjunct to the restraint on hospital operating expenses provided by our cost containment proposal.

- 4 -

Progress in meeting these problems over the past few years has been considerable. Nevertheless, the need for continued support of health planning at the local, State, and National levels is greater now than ever. We have only just begun to realize the potential of this program. Working together, we can strengthen the planning process so that all Americans can have access to quality health care at a reasonable cost. To reinforce this growing momentum, there are five major areas in which we believe the present health planning and resources development law needs to be changed:

- . The certificate of need (CON) and other regulatory authorities of State and local agencies need to be improved so that they will be able to control capital expenditures and eliminate unneeded and duplicative services more effectively; and in that way, further contribute to restraining health care costs;
- . The role of States and their Governors in carrying out the program needs to be strengthened;
- . The cost effectiveness of planning agencies needs to be improved; and

- 5 -

- . And a demonstration program to encourage the closure and conversion of excess hospital beds should be initiated.

Our proposed bill, I am pleased to note, will correspond in many respects to your proposal, Mr. Chairman. Before discussing the changes proposed, however, let me briefly speak to the accomplishments of this program to date, which are essentially the accomplishments of the health planning agencies themselves, and the many consumer and provider volunteers that guide them.

#### PROGRAM ACCOMPLISHMENTS

Those accomplishments might be best summarized as (1) organizational development and growth, (2) planning and plan development, (3) review and control of proposed capital expenditures, (4) early plan implementation efforts aimed at increasing access to, and the availability of, primary care, and (5) The National Guidelines for Health Planning.

- 6 -

1. Organizational Development and Growth

There now are 203 functioning local Health Systems Agencies (HSAs). Except for Puerto Rico and Los Angeles County, where the original HSAs have been terminated because of their poor performance and failure to meet fully certain legislatively mandated requirements, every part of this country is now served by an HSA. That was not true under the predecessor Comprehensive Health Planning program, when roughly one-third of the United States, and about 20 percent of the total population did not have a local health planning agency.

Over 9,000 consumers (53 percent) and providers (47 percent) serve as volunteers on the present HSA governing bodies. In addition to governing body members, another estimated 35,000 citizens serve on HSA subarea advisory councils and the various committees, task forces, and other advisory groups that HSAs have established to carry out their numerous functions and responsibilities.

- 7 -

This extensive participation by citizen volunteers in the local health planning process is, in our judgment, a most impressive and largely unrecognized program accomplishment. It is essential to the effective functioning of the local health planning process, reflecting a commitment by local communities to health planning as well as providing the HSAs with an array of expertise, viewpoints, and resources they simply could not hire, even if they were able to pay for them. It is conservatively estimated, for example, that approximately one million hours of volunteer time were spent on HSA activities during the past year.

State Health Planning and Development Agencies (SHPDAs) also are functioning in all 57 States and territories. And 51 of those States have established their Statewide Health Coordinating Councils (SHCCs). (Only three States-California, Georgia, and Kentucky--and three territories--the Northern Marianas, Puerto Rico, and the Virgin Islands--do not have SHCCs yet.) Nearly 1,800 consumers and providers contribute their time and skills to serve on the 51 SHCCs.

## 2. Planning and Plan Development

One hundred seventy-one HSAs, or over 80 percent of all agencies, have been fully designated. This means that each has met all the requirements of the law with respect to their governance, organization, and staffing and have been adjudged by the Department to be capable of conducting the full range of prescribed responsibilities and functions. Those 171 HSAs have also developed and adopted satisfactory Health Systems Plans (HSPs) and Annual Implementation Plans (AIPs).

Based on our preliminary analyses of those plans, we find most HSAs have emphasized cost containment, increasing availability and accessibility of care, HMO development, and reducing infant mortality.

With respect to cost containment, for example, 75 percent of the plans include specific goals and objectives dealing with a reduction in beds; and one-third of the HSPs have included shared services and regionalization as part of their cost containment efforts.

Nearly all of the plans reflect a concern for the improvement in the availability and accessibility of health services. For example, 75 percent of the plans contain goals and objectives which identify these needs for medically underserved regions and populations. About one-half of the plans have goals or objectives focusing on regionalization and improvements in primary care delivery aimed at increasing the availability and accessibility of services to the general population.

Furthermore, one-third of the HSPs include goals or objectives concerned with the feasibility of establishing, and the continued support of, Health Maintenance Organizations (HMOs), a proven organizational approach to cost containment through reduction in unnecessary hospitalization.

And 75 percent of the HSAs have developed priority goals or objectives calling for a specific reduction in the infant mortality rates in their areas by 1983.

- 10 -

Most SHPDAs, on the other hand, are still in the process of developing their State Health Plans (SHPs). We anticipate that nearly all State agencies will have completed development of their preliminary SHPs by late this summer.

### 3. Capital Expenditures

Most HSAs have been fully designated for less than a year; only eight SHPDAs have been fully designated to date. Nonetheless, we are beginning to see some tangible evidence of the impact of planning agencies.

One piece of evidence is reflected in the preliminary results of an American Health Planning Association (AHPA) Survey conducted last fall. This study showed that the first 139 health systems agencies studied had, over the previous two-year period, refused to endorse \$1.8 billion in proposed hospital and nursing home projects out of a total \$7 billion considered. These denials affected proposals for 47,826 new



- 11 -

hospital and nursing home beds across the country. Thus, for every four dollars proposed in capital expenditures, one dollar was denied. These savings do not include the long-term operating expenses which, within a few years, would exceed the original capital outlay.

If one counts the total dollar investment in the 139 HSAs and associated State agencies during the same two-year period (\$215 million), the rate-of-return is eight dollars in capital investment denied for each one dollar spent on health planning. Even this reflection of the success of health planning activities does not incorporate the entire regulatory impact of the program.

The evidence reflected in AHPA's survey is reinforced by similar data collected by the Health Insurance Association of America (HIAA). Information obtained from 29 of the 50 States by HIAA indicates that CON disapprovals totalled \$700 million against approvals of \$3.9 billion.

- 12 -

4. Plan Implementation

In addition to holding down unnecessary capital expenditures, there is considerable evidence of HSAs implementing plans which have led to improved access and availability of health care services in underserved areas. For example -

- \* In rural Alabama, an initiative of the HSA in Gadsden has helped the National Health Service Corps place dentists in eleven small towns which never had dentists before. Three dentists began practicing in the fall of 1978. Another eight will open offices in the fall of 1979. All are, or will be, graduates of the University of Alabama-Birmingham School of Dentistry, the only dental school in the State.

- 13 -

- \* The Alameda-Contra Costa HSA identified reduction of the high infant mortality rate in East Oakland as a key priority in its first Annual Implementation Plan. This has led to the allocation of State funds--\$4 million over two and one-half years--to combat that serious health problem. HSA staff are participating in the Maternal and Child Health Task Force set up to implement this initiative in Oakland, and the agency will continue to act as a local coordinator and advocate.

These examples illustrate the kinds of accomplishments we hope to see as a result of HSA efforts to improve the availability and accessibility of care.

- 14 -

##### 5. National Guidelines

In March 1978, the Department published in final form the long overdue National Guidelines for Health Planning. These standards for institutional resources respond to major national concerns with the costs of health care by providing local and State agencies with benchmarks to assist in measuring the need for health services and resources. By contributing to increases in the scope and specificity of community plans, the Guidelines strengthen decision-making.

Much attention has been focused on this first effort at developing National Guidelines. The Department listened carefully to the concerns raised during the extensive process of consultation and responded by clarifying the use of the Guidelines as benchmarks and by providing increased flexibility in the application of the standards through the addition of provisions calling upon local agencies to analyze how the Guidelines apply to their areas and adjust the

- 15 -

standards in light of local circumstances. The Guidelines thus reflect a careful balance between the Federal role in providing National health planning leadership and guidance and the needs of local and State agencies to take account of local conditions.

The second set of Guidelines, a statement of National Health Planning Goals addressing health status, health promotion and disease prevention, and access to care, is currently under development. Work has proceeded on the development of these goals since 1975, involving extensive consultation with State and local health planning agencies, Statewide Health Coordinating Councils, associations and specialty societies, consumer organizations and the National Council on Health Planning and Development. Recent activities have focused on increasing the specificity of the goals in line with the requirement that goals be quantitative to the maximum extent possible and addressing additional issues of major national concern. These revisions will be subject to widespread review and consultation.

State and local plans provide an important source of information for the further development of the Guidelines, and thus we are currently undertaking a review of these plans for potential contributions. The development of the first set of the Guidelines has also led us to an awareness of the gaps in knowledge we have, and thus we have entered into a contract with the Institute of Medicine to study ways to strengthen and extend existing knowledge, data and analytical bases in the health planning field.

#### PROPOSED CHANGES

In the remainder of my prepared statement, I would like to describe briefly some of our proposals for addressing the major areas I previously identified.

1. Cost Restraint

A number of our proposed revisions in the planning legislation, in addition to hospital cost containment and forthcoming capital limit proposals, will be aimed at restraining the inflationary increases in health care costs.

- 17 -

- . Our bill will authorize a three-year demonstration grant program to promote the closure, conversion or decertification of unneeded hospital services and beds. Our proposed authorization of appropriations will be \$30 million for FY 1980 and such sums as may be necessary for the following two fiscal years. This closure and conversion program will provide financial incentives and technical assistance to hospitals to discontinue inpatient hospital services or convert them to fill local, unmet needs. From this demonstration effort, the Department will be able to determine both the costs and benefits, as well as pitfalls, associated with this unique approach to cost containment. From the few studies that exist, short term savings are estimated at about 10 percent of the annual operating costs for closed institutions.
- . To strengthen the health planning program's ability to influence the health system, we will again propose to close a loophole in the State certificate of need program. Having

- 18 -

learned from the well-publicized CAT scanner experience, we believe it is important to cover all acquisition of expensive medical equipment under certificate of need, no matter where that equipment is to be located.

- . The widespread development of Health Maintenance Organizations (HMOs), is one way of controlling the rate of inflation in hospital costs. Our proposal would require State and local planning agencies to apply the same criteria to HMOs and as are applied to other health entities but would authorize the Department to establish other criteria if necessary for HMO development.

## 2. State Role

Our bill will propose several changes designed to enhance and strengthen the role of States and Governors in the implementation and operation of the health planning program.



- 19 -

- . To give the State Health Plan greater visibility, sanction, and public support, our bill will allow the Governor to approve or modify that plan after it has been developed and revised by the SHPDA and SHCC. In addition our bill would require that CON decisions be consistent with the State Health Plan.
- . It would also permit the Governor to appoint the chairperson of the State Health Coordinating Council.
- . In addition, we will propose that a Governor be given greater latitude in requesting redesignation of existing health service areas within the State. Our bill will also permit changing the boundary of a health service area if another boundary would be more suitable for planning purposes. Presently, the boundary of an area may only be changed if the existing boundary ceases to meet statutory requirements.

### 3. Program Effectiveness

In our bill, we will also propose a number of changes intended to enhance the effectiveness of the program and the performance of State and local health planning agencies.

- . It will provide for the review and revision of health systems plans and State health plans every three years. Many agencies have complained, especially the volunteer members of governing bodies, that to require that plans be reviewed and revised annually has the effect of creating a perpetual planning cycle and does not allow sufficient time and attention to be devoted to implementation of priority objectives already established in the Annual Implementation Plan.
- . Our bill will also propose greater flexibility in funding HSAs by replacing the current per capita and minimum grant funding mechanisms with discretion for the Secretary to set funding levels. This authority is necessary to permit a phase in of funding and to encourage innovative advances in local planning.

- 21 -

- . A related change we are proposing would permit returning to conditional status, for not more than 24 months, any fully designated HSA or SHPDA, if it failed to continue to meet all the applicable requirements for full designation or poorly performed its mandated functions.

4. Other

In addition to these proposed changes, there will be several other major changes in our bill.

- . We will again propose to expand the authority of a public regional planning body or unit of general purpose local government that also serves as an HSA. There are currently 25 such units. We believe the regular governing board of the parent body should be given authority to approve the agency's budget, to approve the health systems plan and annual implementation plan produced by the HSA's governing body, and to remove for cause members of the separate governing body for health planning.

- 22 -

- . We will also propose two significant changes regarding Federal sanctions with respect to inadequate State planning programs. Under the present law, the Secretary must terminate any conditional SHPDA that cannot achieve full designation within 36 months. A major requirement for full designation is the existence of an acceptable State CON Program. By this summer, most SHPDAs will have reached the limit on their conditional designation with, I am disappointed to say, few State CON programs which comply with all Federal requirements. The Secretary recognizes that there might be circumstances in which the CON program would be delayed despite reasonable efforts. Therefore we will propose discretion to extend the conditional status of SHPDA beyond 36 months if it is determined that both the agency and the State are making a good faith effort towards enacting an acceptable CON program.

- 23 -

The law further requires that if a State does not have a fully designated SHPDA by September 30, 1980, the Secretary must withhold assistance under the PHS Act and related laws. Our experience with other programs has shown that such a severe penalty is not practicable. We propose as a more appropriate penalty the reduction of the State's formula grants under the PHS Act by 25 percent during the first year of violation, 50 percent during the second year of violation, 75 percent during the third year of violation, and 100 percent the fourth year.

- . Finally, we would not seek extension of the facilities construction authorities. We feel they are counterproductive to our goal of holding down capital expenditures. At a time when the bulk of the evidence clearly points to an excess capacity of 130,000 beds and where future investment should decline, it makes little sense for the Federal government to be subsidizing future growth. Nationally,

- 24 -

however, we will administer the continuing responsibilities of institutions which have received support under Title XVI, such as the uncompensated care, community service, and post-construction loan monitoring activities. In addition, we recognize that the health facility planning concept contained in Title XVI is an indispensable part of health planning. Accordingly, we intend to insure administratively that the SHPDA and HSA plans make adequate provision for the inventory of health care facilities, as well as determining health facility construction and modernization needs, utilizing national criteria for such determination.

In addition to these proposed legislative changes, though, there are several other matters I would like to mention before I conclude. They relate to steps that have or are being taken to improve and strengthen the administration of the programs authorized under titles XV and XVI.

- 25 -

- . The Health Resources Administration has a major, concerted effort already underway to improve and expand significantly its ongoing monitoring and periodic assessment of HSAs and State agencies. In the past year, for example, extended site assessments have been made of 22 HSAs and three SHPDAs.
- . As many of you probably are aware, on October 25, 1978, we issued a Notice of Proposed Rulemaking covering the continuing obligations of Hill-Burton assisted facilities to provide "a reasonable volume of 'free' care." Public hearings on those proposed regulations were held here in Washington on December 5 and 6, 1978. We hope to issue the final regulations later this spring.
- . HRA also has taken a number of steps to improve and strengthen the monitoring of the \$3.5 billion in outstanding loans and loan guarantees and mortgage insurance projects that have been made over the past 10 years under both title VI of the PHS Act and Section 242 of the National Housing Act. Responsibility for administration of the HUD/FHA mortgage

- 26 -

insurance program rests with HEW under an inter-departmental agreement. The recently created bureau of Health Facilities Financing, Compliance, and Conversion, administers the HEW and HUD loan programs.

If I may, Mr. Chairman, I would like to briefly comment on a few of the major provisions in your bill, S. 544. In many instances, we support your revisions for the planning program and are introducing similar amendments of our own, as I have already discussed. Specifically, we would agree with:

- . Expanding the authority of the regular governing board over the governing body in a public HSA.
- . Easing redesignation requirements, especially for interstate HSAs.
- . Returning fully designated HSA and SHPDAs to conditional status if they fail to perform satisfactorily.
- . Permitting more involvement by governors in the State health plan.



- 27 -

- . Easing the requirement that the Secretary withhold funds on September 30, 1980, from States with no satisfactory CON program.
- . Requiring coordination between planning agencies and other cost containment entities within the State especially rate review commissions.

However, in some cases, we will be proposing a different approach.

The escalating costs of health care in this Nation are due, in large part, to excess and unused capacity and underscore the urgency for discontinuance of unneeded hospital services. Our forthcoming capital limit and mandatory guideline proposals will address this problem as will our proposed demonstration program for closure and conversion.

S. 544 requires that State alcohol abuse, drug abuse, and mental health agencies prepare those portions of the State health plan. While we appreciate the role of those agencies, we also feel that the Governor of each State should have the discretion to decide where those responsibilities should be placed.

- 28 -

S. 544 maintains authorizations for a number of health facilities construction activities and development funds. We feel that the construction authorities are counterproductive to our goal of holding down capital expenditures. The Nation needs to reduce, not increase, hospital capacity.

You will recall, Mr. Chairman, that we proposed two years ago, as part of our hospital cost containment effort, to put a \$25 billion cap on annual capital expenditures. While we have not included that proposal in our cost containment bill this year, we remain committed to the general goal of that provision and will soon be submitting separate legislation to accomplish a similar goal.

In addition, we would urge, as we did last year, that certificate of need be expanded to cover all acquisition of expensive medical equipment, no matter where it is to be located.

Finally, we believe that the \$1.7 billion three-year authorization in S. 544 is excessive in light of the President's commitment to holding down Federal spending.

This concludes my prepared statement, Mr. Chairman. My colleagues and I would be happy to answer any questions you may have.

NURSE TRAINING

I am also pleased to have the opportunity today to discuss proposed legislation that would extend Federal nurse training authorities through fiscal year 1980.

The present nurse training authorities, as contained in title VIII of the Public Health Service Act, are, like the Health Planning program, administered by the Health Resources Administration of the Public Health Service.

Mr. Chairman, the Administration's nurse training bill for 1980 supports a targeted approach to Federal assistance for nurse training. This approach recognizes an adequate aggregate supply of nurses and focuses Federal resources on problems of geographic shortages. This bill also assures that nursing students will be eligible for financial assistance on the same basis as other health professions students. We are supporting this same strategy for all health professions training in order to focus support on those programs that will result in better distribution of health professionals to medically underserved areas.

Administration Bill

The Administration bill would authorize appropriations of \$13 million for fiscal year 1980 for the training of nurse practitioners who are currently in short supply. These professionals are trained to provide primary and preventive care, practicing either in complementary or, under certain conditions, substitute roles for physicians. Nurse practitioners have proved to be a cost effective means of increasing the availability of primary care services, especially to underserved areas where they often locate. Fifty percent of a sample of 1974 graduates were employed in either inner city or rural locations. Many nurse practitioner programs include a rural or inner city clinical training component which give nurses experience in these areas. In addition, the Rural Clinics Act of 1977 provides for independent reimbursement of these health professionals in such settings.

The draft bill would also authorize appropriations of \$1.743 million for fiscal year 1980 for special projects, including projects to improve the geographic distribution of nurses, to increase the representation of individuals with disadvantaged backgrounds in the nursing profession, to develop innovative nursing

- 31 -

techniques emphasizing primary care and prevention, to enhance clinical skills, to provide continuing education opportunities, and to provide advanced nurse training.

The Administration's bill would also expand student assistance opportunities for nursing students. The bill would eliminate the 10 percent limit on National Health Service Corps (NHSC) Scholarship support available to health care practitioners other than physicians and dentists. This program offers large scholarships with a definite service commitment, and has proved to be the most effective means available for attracting health professionals to underserved areas. In addition, the bill would broaden the Health Education Assistance Loan (HEAL) authority to include nurses in graduate programs, and would repeal a restriction on the eligibility of nursing students for National Direct Student Loans. These proposed changes, along with the current general student assistance programs, including Basic and Supplemental Educational Opportunity Grants, administered by the Office of Education, would assure nursing students access to financial aid on the same basis as all other undergraduate and graduate health professions students.

S. 230

In contrast to the Administration bill, S. 230 would extend for one year at an authorization level of \$125 million, the full array of expiring authorities under the nurse training provisions (title XIII) of the Public Health Service Act. The authorization levels in S. 230 exceed by over \$100 million the nurse training funding requested by the President for 1980. Moreover, the graduate level support and general nursing student assistance programs proposed for extension by S. 230 are inconsistent with the Administration's efforts to reduce Federal spending and its health professions training policy to focus limited resources on programs designed to increase the emphasis on primary care nursing and to alleviate geographic maldistribution.

DISCUSSION

For the past 22 years, the Federal government has provided substantial support for nursing education. From 1956 through 1978, about \$1.5 billion has been awarded for student traineeships, loans, and scholarships; for construction and basic support for nursing education programs; and for projects to improve nursing education and recruitment.

- 33 -

With the help of this Federal support, there has been a marked increase in the supply of nurses in recent years. Graduations from nursing education programs have more than doubled since the enactment of the Nurse Training Act of 1964. In addition, an increased proportion of the nurse population is actively employed in nursing today.

Through actions of the private, State and local governmental sectors, combined with prior Federal assistance, we have put in place the capacity to produce an adequate supply of nurses to meet future needs. Recent CBO and HEW analyses of nursing supply and demand have concluded that the supply of nurses, through 1990 and 1985 respectively, is likely to be sufficient to meet the demands resulting from probable changes in the health care system.

The Administration thus opposes the continuation of general subsidies to nursing schools. It is the Administration's view that Federal support for health professions training should focus primarily on service commitment scholarships and direct placement of needed health professionals in scarcity areas through the National Health Service Corps. For students not wishing to undertake such commitments, the health education assistance loan program in the Office of Education is available.

Mr. Chairman, due to:

- . the adequacy of current and projected nursing resources,
- . the limited impact of Federal assistance on increasing the overall supply of nurses,
- . the inability of increased aggregate supply to meet the problem of maldistribution,
- . the President's desire to scrutinize Federal expenditures of marginal effectiveness in his efforts to control unnecessary expansion of the Federal budget,

investment in the acceleration of the output of professional nurses no longer competes favorably with more pressing health priorities.

The Administration currently is conducting a major review of its support for health professions training, with the aim of developing a new legislative proposal covering various HEW programs affecting health manpower training for fiscal years 1981 and beyond, which address problems of geographic and specialty distribution.



- 35 -

We have been looking not only at how the health professions programs help meet our needs, but also at their relationship to other Federal programs or policies that affect the supply of health professionals. The implications of various types of health care financing schemes on the supply and distribution of professionals still need to be considered. Finally, we must take into account the effects of health professions programs on future health service costs.

Mr. Chairman, the Administration's manpower proposal will take account of the key part played by nurses in the provision of health care in our society. Nevertheless, we believe it is essential to use the necessary extension of nurse training authorities to make mid-course corrections in the evolution of an appropriate Federal role in nursing education. Congressional consideration of the comprehensive health manpower amendments may not be concluded until the end of this Congress. The need for redirection of Federal nursing programs, as well as the current economic climate and the shared Executive and Congressional resolve to decrease the Federal deficit, lead us to urge the Congress to enact the Administration's legislative proposals to provide focus to our nurse training activities.

- 36 -

We we would now like to present our views on S. 590, the Clinical Laboratory Improvement Act of 1979, and to report on the activities of the Department with respect to the regulation and improvement of clinical laboratories. As you well know, clinical laboratories represent a significant part of the Nation's health services. The importance of laboratory tests in the assessment of health and in the diagnosis, treatment, and monitoring of disease demands efficient, careful safeguards to assure the highest quality of test results.

Let me assure you that this Administration shares your concerns about the need for quality, the prevention of fraud and abuse in the reimbursement of these services, and the containment of costs of clinical laboratory and other health services. The Department has already initiated steps to accomplish these objectives under current authorities. We believe that S. 590, with the changes we are recommending, will permit us to continue the progress made and to achieve our mutual goals.

Current Programs

The Department's involvement in the regulation and improvement of clinical laboratories derives from Title XVIII of the Social Security Act (Medicare) and Section 353 of the Public Health Service (PHS) Act (Clinical Laboratories Improvement Act of 1967-CLIA 67). In addition, the Federal Food, Drug and Cosmetic Act and other sections of the PHS Act impact on clinical laboratories with respect to blood banking services, medical devices and diagnostic products, health planning, and the credentialing and training of health manpower. Also, the Department is involved in the direct provision of clinical laboratory services in the Public Health and Indian Health Services facilities, as required in the PHS Act.

Recent Progress

Even before introduction of clinical laboratory legislation, the Department attempted to correct many of the problems addressed by the bill, and for the past two years resolution of program differences has been a top priority of this Department. Working closely with the Administrator of the Health Care Financing Administration (HCFA), under current authorities in the Social Security and Public Health Service Acts, we have made considerable progress, despite some impediments, in improving the uniformity and

effectiveness of our laboratory activities. Progress has admittedly not been as rapid as we would have liked, but we can attest to the following substantial improvements.

#### Coordination within the Department

Several important steps have been taken to improve the administration and coordination of the Department's clinical laboratory programs. For example, the Interagency Agreement on the Regulation and Improvement of Clinical Laboratories that was consummated in 1975, has been updated and improved. The revised document sets forth the division of responsibilities between the Public Health Service (PHS) and HCFA, and is designed to maximize the distinctive competencies of each of these agencies in the regulation and improvement of clinical laboratories.

Since January 1978 under the agreement, HCFA has been responsible for administering the regulatory functions of both the Medicare and CLIA programs, through the Medicare provider certification system using state agencies. This consolidation not only reduces the amount of overlap

- 39 -

and inconsistency between the programs but also the number of inspections to which laboratories are subjected.

The PHS is responsible for the development and promulgation of the scientific and technical standards, including personnel requirements, for all clinical laboratories covered by the CLIA and Medicare programs. The PHS, through the Center for Disease Control (CDC), will also monitor the performance of the State regulatory programs and the several accrediting and approval organizations, such as the Joint Commission on Accreditation of Hospitals (JCAH) and the College of American Pathologists (CAP), in the application of these standards.

The Department also is taking steps to reduce the overlap in inspections between the regulatory program for clinical laboratories and the regulatory program for blood establishments. Currently, hospital blood establishments which include a transfusion service are inspected under Medicare as part of the hospital certification process. These same establishments also are inspected by the Food and Drug Administration under that agency's registration and licensure program for blood establishments. In response to the concern over this duplication of inspection authorities, in the future, only one Federal inspection will be necessary in hospitals whose

- 40 -

blood establishment performs transfusion services exclusively. Since HCFA will be responsible for inspecting those hospitals' clinical laboratories, including the laboratory's transfusion services, it will not be necessary for FDA to perform a separate inspection. FDA has agreed to accept the determinations made by HCFA. Approximately 2,500 hospitals would be affected by this arrangement.

Another example of Departmental coordination is our Task Force on Clinical Laboratories, which was established in December 1977. The Task Force, which is comprised of representatives of those PHS agencies whose programs impact on clinical laboratories and representatives from HCFA, provides a Departmental forum for the identification, exploration, and resolution of problems and issues pertaining to clinical laboratories. Significantly, we recognize the value of external expert advisory assistance, and the Task Force has met, on an ad hoc basis, on several occasions with representatives of a number of professional and scientific groups in the laboratory field. The Task Force has engaged their assistance in the development of policy recommendations on a variety of substantive matters, such as requirements for clinical laboratory personnel, quality control, and proficiency testing.

- 41 -

Quality of Clinical Laboratory Services

Mr. Chairman, as you know, insuring quality through standards is a primary objective of the Department's clinical laboratory regulatory programs.

In the past, however, there have been differences in the content of the standards and the manner in which these requirements have been applied by the regulatory agencies. Under Medicare, for example, different standards were prescribed for independent laboratories and those laboratories in hospitals. In large part, the independent laboratory standards were more stringent than those applied to Medicare hospitals. The CLIA standards for interstate laboratories, some of which also participate in Medicare, were essentially adopted as the Medicare requirements for independent laboratories. Additional difficulties were encountered because the Medicare program accepts for certification purposes hospital laboratories accredited by the Joint Commission on the Accreditation of Hospitals (JCAH) and the American Osteopathic Association, (AOA), whose standards were not consistent with the Federal standards.

The Department has been working for some time to eliminate these differences and to adopt standards that can be applied uniformly to all federally regulated clinical laboratories.

- 42 -

In 1978, the Medicare independent laboratory requirements for quality control (which are equivalent to the CLIA requirements) were extended to laboratories in Medicare hospitals, thus making such standards uniform for all federally regulated clinical laboratories. Presently, we are drafting for publication as a Notice of Proposed Rulemaking (NPRM), in the Federal Register, a new set of uniform personnel standards for clinical laboratories. Together with requirements for quality control and proficiency testing, these standards will constitute a set of requirements for all federally regulated clinical laboratories.

During our assessment of differences between quality control and proficiency testing requirements for independent and hospital laboratories, the Department determined that the requirements for independent laboratories were higher than those which the JCAH and AOA prescribed for laboratories under their hospital accreditation programs. In order for laboratories in JCAH-and AOA-accredited hospitals to continue to have "deemed status" under Medicare (i.e., determined to be in compliance with the Medicare requirements by virtue of the hospital's accreditation), and to be exempt from direct onsite inspections by State Medicare survey agencies, the JCAH and AOA had to upgrade their standards and laboratory survey process so as to make them equivalent to the Federal interstate requirements.



- 43 -

Consistent with its objectives to achieve uniform standards for all clinical laboratories, HCFA and CDC have jointly worked closely with the JCAH and AOA to upgrade their standards.

In January 1979, the Department determined that JCAH standards were equivalent to the Federal standards and JCAH could continue to provide "deemed status" to their hospitals. The Department is continuing to work with the AOA to upgrade its standards and hopes to make a determination of equivalency in the near future.

We believe that all these actions will accomplish the objectives of a well coordinated and uniform regulatory program for clinical laboratories.

#### Fraud and Abuse

We know the laboratory services are vulnerable to a host of inappropriate practices.

The Office of Inspector General and HCFA's Office of Program Integrity have initiated a special joint effort to analyze the billing practice of independent commercial laboratories. In November 1977 a pilot review of laboratory practices in California was initiated. The purpose of the review was to design

- 44 -

and implement computer applications to identify providers with aberrant billing practices. Additionally, audits were made of selected providers to test the efficacy of the computer programs.

Numerous, substantial improper payments were found, and criminal investigations are underway at four labs. Physicians were also audited and were found to have submitted improper claims. In many cases we have seen evidence of discriminatory billing of the Medicare program or apparent collusion between labs and physicians.

In April 1978 we launched the operational phase called Project Integrity II. The Inspector General has made the design and detection techniques available to all States. To date, seven States are participating in the project and several others have been briefed and are considering participation.

In P.L. 95-142, the "Medicare-Medicaid Anti-Fraud and Abuse Amendments", the Congress has provided us with valuable tools to combat these erosions of public funds.

- 45 -

The provisions of S. 590, which authorize the revocation of laboratory licensure when the owner has been convicted of a criminal offense or is guilty of any other prohibited act, will strengthen our ability to eliminate payments for fraudulent and abusive laboratory services.

S. 590

We support the basic objectives of S. 590: to create a coordinated authority for the Department's clinical laboratory programs, to establish uniform standards for all clinical laboratories subject to Federal regulations, to eliminate duplication in the administration of the programs, and to provide additional authority to deal with cases of fraud and abuse. Administration support, however, is contingent on certain changes affecting the scope and funding levels of the bill.

As you know we supported similar legislation in the last Congress. The Administration's position, to some extent, has changed because of the success of our administrative actions in bringing about greater coordination and uniformity within the clinical laboratory program, as well as our desire to keep unnecessary Federal spending and Federal regulations in check.

- 46 -

Licensure

We support the bill's concept of licensure that would allow us not only to stop Medicare reimbursement to clinical laboratories determined to be of poor quality, but to close down such laboratories so that anyone using them would be protected.

This extension of authority closes a potentially dangerous loophole in current law which permits negligent laboratories previously licensed under CLIA'67 or certified by Medicare to continue to provide services despite regulatory action which either prohibits operation in interstate commerce or participation in Medicare. We support the bill's extension of authority over intrastate, non-Medicare clinical laboratories that are currently exempt from Federal regulation. This increased jurisdiction is estimated to be approximately 300 labs, which we believe have shown poor quality of laboratory work.

Governmental Laboratories

The bill, however, would expand Federal jurisdiction and authority to cover all State and local government owned and operated laboratories. In general, the Department resists the imposition of requirements on State and local government institutions, unless the need is clearly

- 47 -

indicated. We do not believe the extension of Federal authority to the approximately 500 laboratories which do not already participate in Medicare is warranted here. Furthermore, such laboratories are directly accountable to the public via the normal governmental authorizing and budgeting processes. We would, therefore, recommend that these laboratories be exempted from the provisions of this legislation.

#### Health Practitioner's Offices

S. 590 allows the Secretary the latitude to exempt doctors and other health practitioners in group practices of less than six who perform routine tests or procedures only for their own patients. We believe that this latitude should be extended to include group practices of six or more and to offices where the practitioners do not perform the tests themselves.

The scope and nature of deficiencies in this area are not sufficiently known. Specifically, we do not know whether six or more practitioners constitute the correct size of laboratory that could or should be subject to regulations designed for larger laboratories, and we do not know which

- 48 -

standards or requirements would constitute the most cost-effective means of assuring quality in these sites.

For these reasons we would prefer that this legislation provide for a study of all practitioners' offices as proposed in the House bill, as reported in the last Congress. With the authority granted by such a provisions, we can collect the necessary data to provide Congress with information that is critical to the development of sound pollicy in this area.

#### ADMINISTRATION

We appreciate elimination of the requirement for the establishment of an Office of Clinical Laboratories which would greatly limit the flexibility of the Secretary to manage the Department most effectively. As I have noted, the Department has been justly criticized for the poor coordination of the clinical laboratory programs in the past. However, we believe that the administrative provisions in the bill are unnecessary because of the improvement, clarification and smooth functioning of the Interagency Agreement. Unless this section were administered in a perfunctory manner, imposition of a Director of Clinical Laboratories over the current PHS/HCFA working arrangements would either imbalance our current arrangement by placing the Director in either the PHS or HCFA or inappropriately

- 49 -

require administering the clinical laboratory program from the Office of the Secretary. Not only could this requirement create an unnecessary bureaucratic layer, but it could have detrimental effects on policy.

#### TECHNICAL ASSISTANCE

The Administration opposes the authorization of a new \$30 million program to provide technical assistance to States and laboratories for training, monitoring and other purposes. We believe that such assistance can be carried out using existing authorities and funding levels.

#### MEDICARE REIMBURSEMENT PROVISIONS

Mr. Chairman, I will now turn to the two important provisions of the bill that seek to reform Medicare reimbursement for laboratory services. As you know, one of the most troublesome and costly abuses that we find in Medicare reimbursement for laboratory services is the practice of some physicians who add to their bills substantial markups for service performed by an outside laboratory. This practice, I should add, is considered improper not only by HEW but by the American Medical Association as well.

We strongly support the bill's intent to stem this abuse. We are concerned, however, about the potential impact of these provisions on physicians' decisions to accept assignment,

and therefore on beneficiaries' out-of-pocket costs. Moreover, we have authority under Title XVIII of the Social Security Act to issue regulations to deal with the problem to which the proposed amendments are addressed. We oppose mandating these specific provisions because we are concerned that they limit our authority to adopt other reimbursement options for laboratory services. Options currently under consideration include prohibiting physicians from billing for services performed by independent laboratories, negotiating with laboratories to establish fee schedules, and include laboratories' discounted prices to physicians in the information used to develop prevailing charges.

We would like to work with the Congress in an effort to develop a more comprehensive approach through both regulation and legislation, which would not only curb physician markups for independent laboratory services but also strengthen our ability to limit reimbursement for all diagnostic laboratory tests, encourage acceptance of assignment and thus protect beneficiaries from extra billing from laboratories as well as from physicians.

Mr. Chairman, the second set of Medicare reimbursement provisions concern the methods by which Medicare reimburses hospital-associated physicians. These provisions are designed to deal with the major reimbursement problems concerning



- 51 -

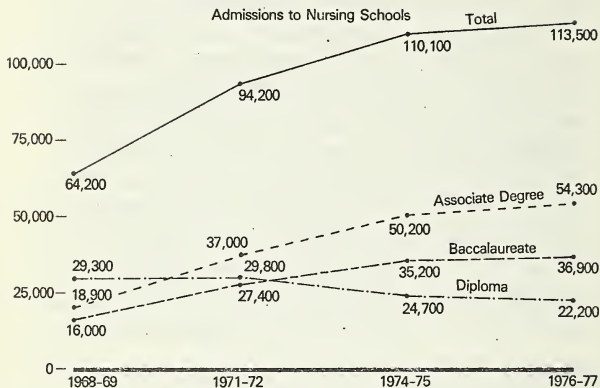
hospital associated physicians. The bill would more strictly define what services performed by these physicians can be reimbursed on a fee-for-service basis. In addition, the bill would limit payments made under percentage and lease arrangements and would require physicians to accept assignment as the quid pro quo for the current waiver of Medicare cost-sharing. We support the objectives of these provisions but believe that sufficient statutory authority currently exists to deal with most of these problems. We believe that we can work together with the Congress to assure that Federal programs do not bear any excessive costs associated with reimbursement of these physicians.

#### SUMMARY

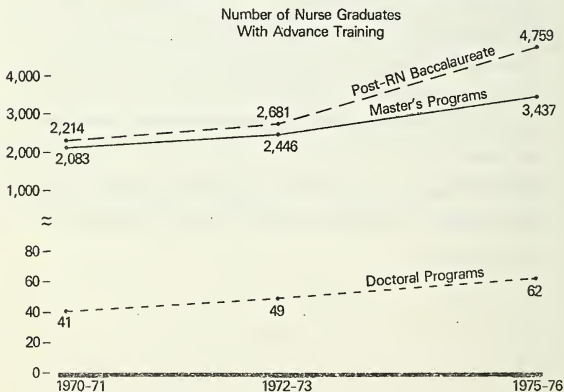
The Department concurs in the need for a well-coordinated effort to assure the public that clinical laboratory services are accurate and of the highest quality. Senate leadership in pursuit of this goal has paralleled a record of recent administrative accomplishments. We hope this progress meets with your approval and would welcome the opportunity to work with the Committee to fashion legislation that provides for a limited extension of regulatory authorities, enhances program coordination and aids our efforts to curb fraud and abuse.

This concludes my prepared statement, Mr. Chairman. My colleagues and I would be happy to answer any questions you may have.

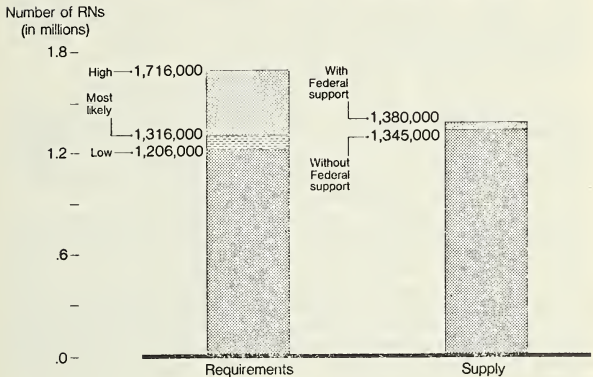
## Admissions to Nursing Schools Have Increased



## The Number of Nurses Graduating With Advanced Training Is Higher



## On Balance, by 1985 the Aggregate Supply of Nurses Will Fall Within the Range of Aggregate Demand



Senator KENNEDY. We have here the recent nursing study, the nursing study that was made available to us last evening. I have not had a chance to go through that or examine it in any detail.

I guess Dr. Foley is representing the nurses here today.

Dr. RICHMOND. Yes; he is representing the Bureau of Health Manpower.

Senator KENNEDY. Is the head of the nurse division here?

Dr. FOLEY. I do not believe so, Senator. The director of the Bureau of Health Manpower is here, Dr. Whiteside.

Senator KENNEDY. I did not know if the head of the nurse division was here or not.

Dr. RICHMOND. She apparently is not.

Senator KENNEDY. This document will be most useful for us because we have such enormous disparity on the question of the numbers and there is healthy division of opinion about this issue, not only of the numbers but of the training and the other aspects of it.

I think it will be enormously valuable for us to have it and to examine this. We also ought to have the basic documents that went into the makeup of the draft—the raw data. Would you make those available to us?

Dr. FOLEY. We could do it within this week, Senator.

Senator KENNEDY. I think that would be helpful.

Dr. FOLEY. Senator, if I might, I would like to apologize to the Chairman and to the other members for the lateness of the report from the Department. What had happened in the past was that

there had not been a critical look at the assumptions of the various studies and other assumptions that may not have been included.

Various parts of the Department were involved in that discussion. It was recently that the assumptions of the assistant secretary of planning and Evaluation in the Department were brought to bear in terms of the health plan the administration is considering.

But, again, I apologize for the lateness of the report. We would be glad to send you the backup documents to that report.

Senator KENNEDY. It is only 14 months late.

Dr. FOLEY. I think it is a much better document, though.

Senator KENNEDY. Good, then all that time was well spent. [Laughter.] In a serious manner, we would like to examine both the document, the assumptions, how you view it in relation to health insurance. I would like to see how it is consistent with the other basic material that was supplied. I think it will be very helpful to our committee, and I appreciate your responsiveness.

I do not intend to take a great deal of time on the issues of the adequacy of numbers and others. We discussed that at some length on the floor earlier this week and at other times.

Even though my part of the country has the greatest concentrations of numbers according to studies that have been done, we have 150 budgeted vacancies at Mass General Hospital, over 120 at Boston City Hospital, and we have serious issues and questions with the new responsibilities that nurses have taken about nurse training and about the nurses desire to upgrade their skills, to assume new responsibilities.

I do not see, myself, how you can expect people who are in the area anywhere from 9 to 12 or maybe even at the top maybe \$15,000 a year be able to either take the time off or afford the tuition to get the necessary kind of training to assume those responsibilities.

I know that the administration supports the fact that they should be able to upgrade skills. We have however a serious kind of division about what is the best way to do it.

Others will question you about it, and we will look forward to examining the study.

In the area of clinical labs we have seen the difficulty in this committee over the periods of the Congress--Biotest laboratories of New Jersey, information that was being provided or false information being provided to the Food and Drug Administration upon which they were going to make scientific tests which have enormous implications. We know you Dr. Richmond deplore this kind of activity and want to work with us.

But even in the Federal laboratories, as I understand, there is some important discrepancy in the areas, for example, in the Indian Health Service which have been under the Federal jurisdiction.

I do not know if there is any comment that you would want to make on the degree of proficiency and expertise and reliability under those labs that are being even run by the Federal system let alone those that are caught up in a matrix of different jurisdiction and administrations and procedures, whether in States or the interstate system.

Do you want to comment briefly?

Dr. RICHMOND. I just might comment very briefly, Senator, particularly on the Indian Health Service Laboratories.

Senator KENNEDY. You are familiar with the draft report, I guess.

Dr. RICHMOND. I am familiar in general.

Senator KENNEDY. It says a total of 10,700 deficiencies were identified at 74 Indian Health Service Laboratories responding to the self-assessment. This is an average of 145 deficiencies per laboratory. The number ranges from a low of 49 in Albuquerque area to 323 for a laboratory in the Navajo area.

And based on this data few, if any, of the Indian Health Service Laboratories are adequately quality controlling the services they provide.

I know my colleague, Senator Javits, will go into a number area just on quality, but I am wondering if you will give me the opportunity to inquire of you in this area.

Dr. RICHMOND. Yes, Senator, the laboratories in the Indian Health Service Hospitals and ambulatory care facilities are experiencing a great deal of difficulty. We, however, feel they should meet standards.

CDC has established those standards for HCFA as well as for our laboratories, and we hope that the HCFA standards will be adopted, and I think, in general, have been adopted by the various State laboratories.

But to return for a moment to the Indian Health Service laboratories, just 3 weeks ago I visited some of those facilities in remote sites, and I think one gains a very considerable appreciation of the great difficulties under which the professional staffs in those areas are working.

There is virtually no trained personnel available, and we are going to make a very determined effort to see if we cannot identify some way by which we can get better laboratory services in place in those areas.

Technical assistance, for example, in the taking of X-rays. I visited several X-ray departments where technicians just were unavailable for the position. It was the physician themselves who actually performed the taking of the X-rays as well as the reading of the X-rays.

So we are very sensitive to the problem. We are going to be working very closely with Dr. Emory Johnson, who directs the Indian Health Service to see if we cannot upgrade those programs, but it is a difficult area.

Senator KENNEDY. It is difficult, as you pointed out, but the question is given the situation in laboratories in remote areas or in other areas somewhat removed from the mainstream, or even those that are considered to be right in the heart of the industrial areas, are they performing or complying to the types of standards which are necessary to make the kind of scientific and medical judgments? That is what has motivated this bill.

Now to discuss the planning legislation, I am obviously concerned about the budget level. I know you have said the program saves \$8 for every \$1 spent. It seems to me to be a wise allocation of scarce resources even for the short or long term.

In this area, as I understand, in real dollars, the HSA's will actually get smaller grants in 1979 than they got in 1978. Is that your understanding?

Dr. FOLEY. Relatively, that is the case, Senator. We think that the program, having gone through the startup stage, has become more efficient. But we also recognize, given the scarce resources we have, that we are asking the health planning agencies to do a great deal over this next year.

Senator KENNEDY. We are working closely with you in the areas of cost containment and others. It seems an important opportunity for the savings of real money. It is just bearing that out. We are going to face some tough issues on that, of course, in the future, but it seems to me to be—the second is the balance of power, the concern that we have about the virtual veto of the Governor with the administration's proposal.

We have worked out a rather delicate balance about consumer input, local participation, and its difficult allocations of power that I would say that you have come down ultimately in a stronger position, vis-a-vis, this balance in terms of the Governor, than we might assume.

Let me just move to a third area, because I want to move the hearing along, and that is in the area of cost containment. If the hospitals are interested in the termination or the closing of the various facilities, should they be allocated at least some consideration in the cost containment which would permit them to raise the additional revenues which may be necessary for the termination of facilities or are we inconsistent in our desires to put, on the one hand, the limitation on various hospitals and, on the other hand, trying to encourage them to reduce surplus facilities. Should we be thinking in those terms at all, give them some kind of encouragement?

Dr. FOLEY. I believe, in this case, Senator, that we, in the administration and you are in agreement. Let's take, for example, a situation where there are three hospitals in a community.

One hospital would like to get out of the health care industry but has a debt service to try to abolish; and the other two hospitals have been working cooperatively. We think there ought to be mechanisms so that we would, through the closure and conversion approach, be able to work with those hospitals to basically develop a solution that preserves access to gage in the local community but also allows one hospital to close.

Senator KENNEDY. I was thinking more in the terms of permitting the revenues of the hospital to exceed the standards so that they can raise the resources to close it, or change, or alter the function of surplus beds or whatever.

If we put the cap on the particular hospital and, on the other hand, we want them to terminate facilities that they are going to terminate, they have to raise the resources. They do not get the moneys in terms of grants under one of the proposals which we passed last year which are basically very limited resources for change.

Should we be flexible on that? I might put the question to you and see if you would give some thought to it.



Dr. FOLEY. Would you, please, Senator; and we would come back with a formal response.

Senator KENNEDY. Senator Schweiker?

Senator SCHWEIKER. Thank you, Mr. Chairman.

I would like to address some questions, Dr. Richmond, to the Health Planning Act, and I want to say we are pleased to see the areas of agreement that you have highlighted in your testimony which this committee has worked long and hard on, and there are a few other suggestions in your statement that I find of interest.

I would like to explore a few of them. You suggest, on page 20 of your statement, that instead of doing a yearly plan, that we do a plan every 3 years.

I wonder if you would elaborate a little bit on why you advocate a 3-year planning process as opposed to an annual one?

Dr. RICHMOND. Senator Schweiker, I would be glad to make some comments and then ask Dr. Foley, perhaps, to elaborate as well. The development of a planning document and a plan is a very complex process. Having worked at the State level not too many years ago, I think I have experienced the complexity of this process and the amount of time it consumes. If one endeavors, for example, to try to develop a plan each year, one no sooner concludes the planning process than one immediately begins again, without having an opportunity to see what the implications of that plan have been. In my experience, trying to have an annual or even a biennial plan tends to promote a process by which successive plans begin to look very much alike. There is very little opportunity to have some interval in which to reflect on the experiences which have been gained and to redevelop a plan in a fresh way.

We thought a 3-year interval would provide for that opportunity. Dr. Foley may also have something to say on this issue.

Dr. FOLEY. I would just add, Senator, that we have seen in some of the large HSA's in the country that the plan is approximately 1 foot thick. We think, consistent with what Dr. Richmond has just stated, that it takes a lot of time for them to negotiate, within a community, the many pieces that eventually become the plan. For example, the question of merger which occurred in your State. It takes a great deal of time to get hospitals to work together to accomplish what has been detailed in the plan.

We are in danger of doing a lot of planning for planning's sake, without any outcome. So what we have emphasized here is a 3-year process. If, during that interval, there is a piece of the plan that clearly becomes obsolete or ought to be changed, then that section could be amended, rather than having the whole plan redone each time. That is our basic intent.

Senator SCHWEIKER. I think the proposal makes a lot of sense. I certainly would favor it as far as I hear you talk, because it just seems to me with the kind of paperwork and redtape you develop, you are doing more planning and administering, and while planning is an integral part of it, administering is also an important part. I certainly support that.

On page 28, you criticize, maybe rightly so, our 3-year authorization as costing too much at \$1.7 billion. What are your figures? What do you propose?

Dr. FOLEY. We are proposing, for this coming year, \$115.4 million for the health systems agencies and \$30 million for the State agencies, making a total of \$145.4 million.

We intend to track the performance of these agencies over the next 6 months, and then, after our budget development process, come back for authorizations for the next 2 years. Between now and October of this year, we have to make a defense within the administration for how successful this program is. We will be making our budget projections on the effectiveness of the health systems agencies and the State health planning agencies.

We assume that if they maintain the rate at which they are now going, given the successful outcomes we have been able to identify in terms of access and cost containment in each HSA and SHPDA in the country, that we would probably be able to argue for at least a modest increase in the next year, depending upon the budget constraints.

Senator SCHWEIKER. Can you give us a figure, because it is OK to say \$1.7 billion is too high, and it well may be too high. I may agree. But we have got to write a bill up in the next few weeks. I gather you have one figure but not the second- and third-year figures.

Dr. FOLEY. That is correct.

Senator SCHWEIKER. Do you have an estimate? I mean, how can \$1.7 billion be too high if you do not have a second- and third-year figure? You must have something in mind.

Dr. FOLEY. We would be prepared to come back with an answer, Senator Schweiker, but I would have to confer with others. Frankly, there has to be some negotiation, between now and October, between the Department and OMB over what we feel has been a successful outcome of the planning program.

Senator SCHWEIKER. When can you give us an answer? I hope not October. We've got to pass a bill in the next month, hopefully.

Dr. FOLEY. We would attempt to come back with an answer to you in the next few weeks, Senator.

Senator SCHWEIKER. Fine. I am not disagreeing with what you are saying. I just would like a concrete, specific figure that we can compare with ours.

On page 23 of your statement, you do not seek extension of the facilities construction authority. You feel they are counterproductive, et cetera.

I wonder if you would capsule your position on this.

Dr. FOLEY. Senator, we have clearly identified that we have an overbedding situation in this country. We recognize that hospitals have been able to expand their plants or modernize by going to the bond market.

We recognize that in some States, such as New York State, they have put a moratorium on the letting of bonds for hospital modernization and construction because they recognize the overbedding situation.

We think in this situation, at least for the next 2 to 3 years, that we ought not to be recommending Federal financing for these types of expenditures, particularly in areas that are overbedded.

So, as a consequence, we are not recommending a continuation of that program. However, that could change in subsequent years if it



were demonstrated that, in various parts of the country, there was not an overbedded situation and there was a need for assistance, particularly for public hospitals.

Senator SCHWEIKER. All right. We will certainly take a look at that recommendation.

That is all I have, Mr. Chairman.

Senator KENNEDY. Senator Javits?

Senator JAVITS. Thank you, Mr. Chairman.

First, gentlemen, I join my colleagues to thank Dr. Richmond for being here today and helping with these matters. I appreciate those suggestions that you have made for cooperatively working with us. As far as my staff and I are concerned, we will do our utmost to fashion with you what is an effective provision. I also appreciate your general endorsement of the CLIA legislation.

One observation on that. We have included in our bill the provisions respecting medicare providers only because we do not know as yet what the Finance Committee will do. That is their jurisdiction.

It could be ours but normally it is theirs. Senator Talmadge is leading the effort before Finance. It would be our purpose to see what the Finance Committee has found when we mark the bill and then act accordingly, bringing it to the floor if necessary, but always bearing in mind that when they speak, we listen and pay strict attention to what they wish.

I have a few questions while we are on CLIA. I will come back to the nurses. I notice that you do not propose to omit from the ambit of the regulatory scheme the Indian Health Service Laboratories.

Obviously, that has very, very grave deficiencies. I have before me a report which I would like to include in the record, respecting these particular laboratories. I will just read one short paragraph:

A total of 10,738 deficiencies were identified out of 74 IHS laboratories responding to the self-assessment,

which they made.

This is an average of 145 deficiencies per laboratory. The number ranged from a low of 49 in the Albuquerque area to 323 deficiencies with the laboratory in the Navajo area.

This report is dated 1978, addressed to the Director of the Indian Health Service, November 3, 1978, from the chairman of the task force to assess IHS laboratories. I hope you will give that your attention; I am pleased to see that you have abandoned the idea of exempting Federal laboratories.

But I would like to ask you this. You spoke of 500 laboratories concerned at the State and local level. What assurance, Dr. Richmond, do we have that they are any better? What evidence do we go on in saying that they ought to be omitted when even the Federal laboratories in the Indian Health Service, at least, are in such horrible condition?

Dr. RICHMOND. Well, sir, I think to take particularly the Indian Health Service laboratories, for a moment, as I indicated in response to Senator Kennedy, the problem there, not uncommonly, is one of location. There is great difficulty in establishing appropriate personnel in many of those relatively remote areas.

The Indian Health Service laboratories that are more centrally located tend to do significantly better and, as you have indicated, we are in the process of taking a hard look at the improvement of those laboratories.

Concerning State and local health department laboratories, I think it is fair to say that there has been a tradition in this country of States and local health departments conducting relatively reliable laboratories, and certainly in my experience, they have in general functioned quite well.

Also, I would point to the fact that our agency that monitors and has developed the standards as you know for the monitoring of the quality of laboratory work, CDC, is involved very intimately with State health departments and we certainly will be directing the attention of State health officers and local health officers to this issue. We will suggest to them that they exercise the CDC standards.

I think that a great many of them already are, but it would be well for me to ask CDC to see to that extent the State laboratories are, indeed, doing this, and I would be happy to do that.

Senator JAVITS. Dr. Richmond, we appreciate that, but may I point out that many of our struggles highlighted by the civil rights struggle were based upon the fact that States' rights have to be matched by State responsibility.

The citizen who receives this service from a State or local laboratory is also a citizen of the United States. Now, if they do an acceptable job, I am all for letting them do it. However, if they do not obtain accurate results, I will not condone letting the citizens suffer, because his local laboratory is lax.

So I hope in this respect, because the cost is very minor compared to the costs at stake, that we can work out a provision which will follow that principle. If they do the job, great. But if they do not, we should not make exceptions because they are a State or local agency.

I think that is the big revolution in American law in terms of the Federal Establishment. We will work with you.

Dr. RICHMOND. I am very sensitive to that, Senator, and as I have indicated, CDC has many relationships with State and local health departments more generally. I think it would be appropriate for me to ask them to review the quality of work in State and local health departments.

Senator JAVITS. Bearing in mind that they are not generic, some are good and some probably are pretty bad.

Dr. RICHMOND. I happen to know the State laboratories in your home State and they are superb.

Senator JAVITS. Well, I wish that were true of them all, but we are not superb in everything either.

May I now ask you about this interagency agreement? No one appreciates more than I that perhaps under the impulses of this legislation and the fact that it has stimulated thought and discussion, good changes are being made. I hope they will continue to be. That is what we are all about. It is a performance standard that I am interested in.

How long has the current interagency agreement proposed been under negotiation?

Dr. RICHMOND. That interagency agreement has been functioning, and Mr. Schafer and I have signed such an agreement establishing this relationship.

Senator JAVITS. You have already done that?

Dr. RICHMOND. Yes.

Senator JAVITS. So it is now final?

Dr. RICHMOND. Yes; as of March 17.

Senator JAVITS. It needs no further approval. How long did it take to negotiate it?

Dr. RICHMOND. Well, I think functionally, we have been working as though we had an agreement virtually since I arrived in my office some 20 months ago. It has taken some time to put this in writing and to formalize it.

But I do not feel that that really at the moment is changing the functional relationship. I might say, Senator Javits, that I have not experienced any difficulty in developing a very close and intimate relationship with the Health Care Financing Administration, bringing CDC and FDA and HCFA together in a very effective way. I think we now have arrived at appropriate divisions of labor.

The process has been going on. We do not need to change the process, but we have consummated a great deal of change in the process so that we think that the CDC role is clear. The regulatory activities are all now being handled by HCFA. FDA will have a minimal regulatory role in clinical laboratories, only where blood products of various kinds are being used.

But I would say we really consummated this relationship, in my view, in a most effective way.

Senator JAVITS. In the view of our provision of the bill, there shall be a director of the centralized administration. In view of the fact that you have now actually entered into this agreement, albeit has taken a long while, we will examine that with you because this is a reform that you could make administratively as well. We will examine that.

Dr. RICHMOND. Correct.

Senator JAVITS. I just have one or two other questions on the CLIA. One of the big problems that I ran into that caused me to take such a deep interest was the lack of professionalism in personnel standards in an area which is so sensitive as this, especially as all of these practices are growing and heavier dependence is being placed upon the testing.

All of us are very much aware of the new attitude we have toward disease, especially in sensitive fields like cancer where testing is really important.

Now, you say in your statement: "Presently we are drafting for publication, as a notice of proposed rule-making in the Federal Register, a new set of uniform personnel standards for clinical laboratories."

Now, that interests me greatly. Do we have any idea as to what you are doing and when you expect to complete these regulations?

Dr. RICHMOND. I think I might ask Dr. Emmott and Dr. Baum if they would like to comment on that.

Dr. BAUM. Thank you. There is now a completed draft of the new standards, and they are at the present time being commented on by the components of the Department. It is our hope that within a

very short time we will have such a proposal before the Secretary for his approval for publication as a notice of proposed rulemaking.

Senator JAVITS. Do you feel that you are really accelerating progressively?

Dr. BAUM. Yes, we do.

Senator JAVITS. Now, is that in response to deficiencies which you, yourself, have found?

Dr. BAUM. It is basically in response to the Secretary's desire and the Department's desire to have uniform standards across all of the programs. This is something that, actually, has been in the making for more than 4 years.

Just recently, however, the Secretary has asked us to try and simplify those requirements so they would be more in line with the objectives of the Department as well as the approach the administration is taking toward regulatory matters.

Senator JAVITS. We must go over that again with you. It is extremely important to me, with respect to this bill, to see how much you really are progressing administratively. We will work with you and try to be creative.

Dr. Richmond, I understand your views about the laboratories in doctors' offices and again, we will work with you constructively. We understand that you favor the House bill.

My mind is not at all closed. I will be very anxious to see how my colleagues feel and try to work something out.

Mr. Chairman, if I can have 2 more minutes on the nurses, that is all.

Let us pass now to that subject of nursing. The aspect troubling me concerning nursing is that you are taking a big gamble upon the situation continuing. Our Congressional Budget Office, for example, conditions its views about nurses on the fact that the status quo of such programs will remain unchanged.

I gather you do the same thing. But is it not a fact that this program will change very materially according to what your recommendations—that large portions of it be eliminated?

For example, you are proposing the elimination of student assistance programs on the ground that they are available through the Office of Education. This is \$44 million out of \$100 million.

Nonetheless, we have no evidence that these funds are adequate. There are many claimants to those funds quite apart from nurses. Secondly, and very importantly, we are giving loan forgiveness to nurses who practice in medically underserved areas.

Is the same thing available under the generalized assistance for all students into which they are going to be cast?

Now, these are questions of providence which it seems to me will have to be answered if we are going to assume, as our Budget Office said that: "If current trends continue, supply should exceed or roughly equal demand in the future."

Your latest report shows that you think we will have just about as many nurses, \$1,300,000-plus, with or without this kind of Federal support. In the absence of implementing information, I must say I doubt that very much.

Remember that our bill is only a 1-year bill. It was my conviction and that of the 29 Senators who joined me, that before dismantling such a structure, we should be very sure of our data. This type of

structure would be difficult to reinstate, due to other career commitments of young people, et cetera. We must use extreme caution in this area where, previously, we have had serious problems due to the shortsighted idea that money could be saved through the abolition of the program.

That is the appeal that I make to you, and any comment you wish to make we would be very glad to hear.

Dr. RICHMOND. Senator Javits, I will make some comments, and then if you so wish, Dr. Foley will elaborate as well. We largely were interested, I think, in capitation as a capacity building device, one which would increase the output of the schools supply.

We think the nursing schools, by and large, have responded very well to that stimulus so there has been the very dramatic increase in numbers of nurses in the Nation, and the ratio of nurses per population unit is much more favorable.

In the past decade, we have gone from 300 nurses per 100,000 people to about 395 per 100,000, a very significant increase. We think the potentiality for maintaining that output is there.

We have to remember that capitation support has not gone to the student, and it is somewhere under \$200 per student per institution, so that it is roughly around 8 percent of the operational costs of those institutions, not a very large proportion of their budget.

We think the potentialities for maintaining the output of nurses are reasonably good. Other issues concern student support. We think student support will be available in other ways, particularly in the form of support that is available to other students at the collegiate level.

Nursing students are at the collegiate level in contrast to many students in other health professional areas.

The other issues that you have addressed, of course, relate to the problems concerning distribution, and I do not think that the distributional problems that we are experiencing will be solved exclusively by turning out larger numbers.

Our experience thus far has indicated that with physicians, dentists, and nurses we just are not experiencing that redistributive effect. We hope to use such devices as the National Health Service Corps, expanding the numbers of places for nursing students in that program, to try to get a redistributive effect.

The loan forgiveness potentialities are matters that I think Dr. Foley can address. We, in general, are in favor of loan forgiveness if those students end up practicing in underserved areas.

We do think that we can target our efforts in more specific ways, and that is why we are leaning in the direction of special projects. We have not eliminated special projects. We think it is well to continue support for nurse practitioners because we think that is a direction in which we will meet some of the service needs in underserved communities more effectively than we are now doing.

I would like to ask Dr. Foley if he would comment.

Senator JAVITS. Doctor, if you would be brief.

Dr. FOLEY. I would only add to what Dr. Richmond has said, Senator, that we know now that we have a million nurses. We know that we are producing 83,000 nurses a year. Half of that is a replacement; 40,000 are new.



On that projection, we know that by 1985 we are going to have the number that is indicated. Discussion should not just be focused on professional nurses. I understand your request for the IOM study which would complement what we are doing in the GMEN-NAC area, but specifically I would urge that we recognize also that in the area of nurses aides, attendants, and orderlies we have an 8.4-percent unemployment rate.

We think that we should target our resources to develop career ladders to help that population be of service throughout our whole hospital and health care system. What we are suggesting is that we have moved, very, very carefully to a strategy using our resources to place graduates in underserved areas and of beginning to work on the other allied health and other types of professionals that would link to nursing.

We must determine what the replacement factors are for certain functions that nurses are performing. We are not saying that all functions of nurses can be done by other health personnel, just as we are not making that statement in the area of physicians. But we do know that some nursing functions have changed. We are looking at factors not taken into consideration in earlier studies. As we have looked at hospital mergers, for example, we are finding that the ratio of nurses in relation to patients is decreasing.

An example would be the Akron hospital structure in which business and labor have moved to begin to reduce the size of the hospital, and as a consequence, staffing levels are being reduced.

Yesterday, as I recall, there was a specific reference by spokesmen from the voluntary sector that, as they move to reduction mechanisms within their hospitals, because of mergers of OB-GYN units, et cetera, they are beginning to reduce the size of the nursing staffs.

This is a factor that we did not consider 2 and 3 years ago and that we all have to begin to look at now.

Senator JAVITS. Thank you, Dr. Foley and Dr. Richmond. Thank you very much. What troubles me is whether collapsing this program in 1 year is really enabling us to see the hard evidence before we act, bearing in mind that it is very hard to recreate the structure.

I am not persuaded, but we will certainly look at your data with great interest. I want to be sure that under the lash of the President's directive that you must cut, you are cutting the bulk.

Thank you, Mr. Chairman.

Senator KENNEDY. I also want to comment on the National Health Service Corps. This is a field that is only open to a few specified nurses needed in underserved areas—nurse practitioners and nurse midwives. The Corps is not a replacement for the Federal assistance now given to those in straight RN training programs.

I want to thank you very much, Dr. Richmond, and associates.

Dr. RICHMOND. Thank you very much, Mr. Chairman, and members of the subcommittee.

Senator KENNEDY. We will next have Dr. B. J. Wilder, M.D., professor of medicine at the University of Florida, and I will ask him to introduce his panel.

Also, would Peyton E. Weary, M.D., of the American Academy of Dermatology join the panel, please.

STATEMENT OF B. J. WILDER, M.D., PROFESSOR OF MEDICINE (NEUROLOGY), UNIVERSITY OF FLORIDA, COLLEGE OF MEDICINE; ACCOMPANIED BY: BRENTA DAVIS, M. ED., ASSOCIATE PROFESSOR, CLINICAL LABORATORY SCIENCES, UNIVERSITY OF TENNESSEE, CENTER FOR THE HEALTH SCIENCES; WILLIAM HAUSLER, PH. D., DIRECTOR OF LABORATORY DIVISION, IOWA STATE HEALTH DEPARTMENT; KATHERINE O'REILLY, EXECUTIVE DIRECTOR, CONSUMER FEDERATION OF AMERICA

Dr. WILDER. I am delighted to be here today, gentlemen. I am Dr. B. J. Wilder, professor of neurology at the University of Florida, College of Medicine in Gainesville, Fla. I am a member of the Florida Epilepsy Foundation's professional advisory board, and a former member of the professional advisory board of the Epilepsy Foundation of America on whose behalf I am appearing today.

With me is Ms. Brenta Davis, associate professor of clinical laboratory sciences at the University of Tennessee Center for the Health Sciences in Memphis, Tenn. Ms. Davis is representing the Coordinating Council for Clinical Laboratory Technology.

Also appearing is Dr. William J. Hausler, Jr., director of the hygienic laboratories of the University of Iowa. Dr. Hausler is representing the American Society for Microbiology, the American Public Health Association and the Association of State and Territorial Public Health Laboratory Directors

Also here with us is Katherine O'Reilly, executive director of the Consumer Federation of America.

I am speaking on behalf of the National Coalition of CLIA to urge that Congress promptly enact S. 590, The Clinical Laboratory Improvement Act of 1979.

The statement I am presenting today is endorsed by a coalition of 18 national organizations, representing health education, scientific, consumer, senior citizen and minority interests.

Our combined membership totals more than 11 million persons. We know that high quality health care cannot be achieved unless all clinical laboratories comply with uniform standards of performance.

S. 590 mandates these standards and thus will assure the kind of health care the American public needs. This legislation is vitally needed. It is designed to resolve three critical problems.

First, we need to assure reliable laboratory test results. When laboratory tests are performed inadequately, erroneous results can lead to incorrect diagnosis and, at times, critically dangerous treatment programs. This happens too often, and the human costs are enormous as are the economic costs.

False negative results, for example, can leave illness or problems undetected, free to worsen, eventually requiring extensive treatment that might well have been avoided had the first test been correct.

On the other hand, false positive test results can cause costly and unnecessary therapeutic problems such as surgery. Moreover, costs amount when erroneous tests lead to repetitive testing.

If I could depart just a moment from my prepared statement, and give some information regarding the experiences in the area of

epilepsy and laboratory procedures dealing with antiepileptic drugs.

One of the major advances in the treatment of epilepsy in the past 20 years has been the development of techniques which allow accurate, quantitative measurement of drug levels in patients blood. These levels can then be used to determine dosage changes to effect maximal prevention of seizures without producing toxic results.

In my capacity at the university and having been instrumental in developing some of these techniques, I have given a number of talks to primary care physicians explaining the advantages of using laboratory data in treatment of epileptic patients.

The response I generally get is that primary care physicians are frightened of using the results because of inaccuracies that have been reported, 50- to 100-percent inaccuracies in lab results reported by many laboratories.

In 1974, the Epilepsy Foundation of America began a quality control program for laboratories which performed these blood levels. This program was set up to assist in improving the reliability of the testing, and an initial study showed that there was less than a 50-percent reliability rate for the drugs tested.

By 1978, the 450 laboratories who participated in this voluntarily, I might add, had improved their reliability to the 85-percent level. However, the number of labs which were performing these tests at the start of the study numbered some 600 laboratories.

By 1978, there were some 4,000 laboratories performing these tests. However, still only 450 had availed themselves of this opportunity of improving their techniques. So this indicates that, left to chance, people often will not avail themselves of the opportunity to improve the procedures they are doing.

We, in the area of epilepsy, feel that this is of vital interest in obtaining accurate lab results. I will return to my text, now, Senator.

Clinical laboratory testing has a significant economic impact in relationship to overall expenditures in the health care field. During 1975, it was estimated that nearly 5 billion tests were conducted by more than 65,000 clinical laboratories for an average of more than 20 tests per person in the Nation.

According to the 1976 findings of the Senate Special Committee on Aging, approximately 10 percent or \$12 billion out of \$120 billion spent for health in 1975 went for clinical laboratory services.

Moreover, by 1980, it is projected that some 8.8 billion tests will be conducted annually at a cost of about \$15 billion. We believe that many of these human and economic costs can be greatly minimized, if not completely eliminated, when laboratory testing is performed in accord with those standards envisioned in S. 590.

Secondly, we need to better protect the consumer. Consumers of health care have a right to expect that testing will be performed in accord with such standards. In particular, because the clinical laboratory field presents such a complex area for the general public to evaluate, most consumers do not have the information needed to determine such matters as which tests and what laboratory should be selected or what procedures should be used to assure the reliability of test results.



Consumers are often left in the dark about the quality of laboratory tests and the impact such testing can have on their own health, and finally, S. 590 is needed to enhance the efforts of HEW to coordinate effectively multiple legislative authorities involving clinical laboratories.

HEW, as mentioned, has tried to do this administratively since 1959 but has not yet completely finalized the process. Given this historical record, we are convinced that HEW needs the authority contained in S. 590 to cope effectively with its responsibilities and insure that the major objective of improved laboratory performance on a nationwide basis is achieved.

In conclusion, let me reiterate that the member organizations of the coalition for CLIA represent a large cross-section of individuals who have a stake in laboratory testing, ranging from those groups whose members actually do the testing to other groups which directly represent consumers who are on the receiving end, in terms of both diagnosis and paying the bills. We know that the solutions to the problems I have described are essential.

The beauty of this legislation is that it resolves these problems. It protects both our health and our health care dollar. In reviewing this bill's predecessor, S. 705, the Congressional Budget Office estimated that legislation such as this would actually save money, up to \$37.07 million in the first year alone.

There is no reason for health care consumers or the Federal Government to tolerate incompetent performance in the laboratory. We believe that it is the clear responsibility of the Federal Government to work with the States within the private sector to assure that reasonable and enforceable standards are adhered to by laboratories.

We believe that CLIA of 1979 is the vehicle for such a program because it provides the basic framework necessary to assure that the public interest and, indeed, our lives are appropriately protected in the delivery of laboratory services.

I thank you for this opportunity to share my views with you. I have several antidotal stories concerning patients but I am sure time is short. I will be happy to respond to any questions and so will the members with me.

Senator KENNEDY. I would like to, if we could, hear from Dr. Weary, and then we will come back to the questions.

[The prepared statement of Dr. Wilder follows:]

STATEMENT  
RESPECTFULLY SUBMITTED TO THE  
HEALTH SUBCOMMITTEE  
OF  
THE SENATE LABOR AND HUMAN RESOURCES COMMITTEE

March 16, 1979

ON  
S.590, THE CLINICAL LABORATORY IMPROVEMENT ACT

TESTIFYING:

B.J. Wilder, M.D.  
Professor of Medicine (Neurology)  
University of Florida College of Medicine  
Gainesville, Florida

(Representing the Epilepsy Foundation of America)

ACCOMPANIED BY:

Ms. Brenta Davis, M.A.D.  
Associate Professor of Clinical  
Laboratory Sciences  
University of Tennessee, Center  
for Health Sciences  
Memphis, Tennessee  
(Representing the Coordinating  
Council for Clinical Laboratory  
Technology)

William J. Hausler, Jr., Ph.D.  
Director of the Hygienic Laboratory  
University of Iowa  
(Representing the American Society  
for Microbiology, the American  
Public Health Association and  
the Association of State and  
Territorial Public Health  
Laboratory Directors)

I am here on behalf of the National Coalition for CLIA to urge that Congress promptly enact S. 590, the Clinical Laboratory Improvement Act of 1979. The statement I am presenting today is endorsed by a coalition of 18 national organizations representing health, education, scientific, consumer, senior citizen, and minority interests. Our combined membership totals more than 11 million persons. We know that high quality health care cannot be achieved unless all clinical laboratories comply with uniform standards of performance. S. 590 mandates these standards and thus will assure the kind of health care the American public needs.

This legislation is vitally needed. It is designed to resolve three critical problems. First, we need to assure reliable laboratory test results. When laboratory tests are performed inadequately, erroneous results can lead to incorrect diagnosis and, at times, critically dangerous treatment programs. This happens too often and the human costs are enormous. So, too, are the economic costs. False negative test results, for example, can leave illness undetected, free to worsen, eventually requiring expensive treatment that might well have been avoided had the first test been correct. On the other hand, false positive test results can cause costly and unnecessary therapeutic programs, such as surgery. Moreover, costs mount when erroneous testing leads to repetitive testing.

Clinical laboratory testing has a significant economic impact in relationship to overall expenditures in the health care field. During 1975, it was estimated that nearly 5 billion tests were conducted by more than 65,000 clinical laboratories (including physician office labs) or an average of more than 20 tests per person in the nation. According to the 1976 findings of the Senate Special Committee on Aging, approximately 10%, or \$12 billion out of \$120 billion spent for health in 1975, went for clinical laboratory services. Moreover, by 1980 it is projected that some 8.8 billion tests will be conducted annually at a cost of about \$15 billion.

We believe that many of these human and economic costs can be greatly minimized, if not completely eliminated, when laboratory testing is performed in accord with those standards envisioned in S. 590.

Secondly, we need to better protect the consumer. Consumers of health care have a right to expect that testing will be performed in accord with such standards, in particular because the clinical laboratory field presents such a complex area for the general public to evaluate. Most consumers do not have the information needed to determine such matters as which tests and what laboratory should be selected or what procedures should be used to assure the reliability of the test results. Consumers are often left "in the dark" about the quality of laboratory tests and the impact such testing can have on their own health.

And finally, S. 590 is needed to enhance the efforts of HEW to coordinate effectively multiple legislative authorities in regulating clinical laboratories. HEW has tried to do this administratively since 1975, but now, more than four years later, has not yet finalized the process. Given this historical record, we are convinced that HEW needs the authority contained in S. 590 to cope effectively with its regulatory responsibilities and insure that the major objective of improved laboratory performance on a nationwide basis is achieved.

In conclusion, let me reiterate that the member organizations of the Coalition for CLIA represent a large cross-section of individuals who have a stake in laboratory testing -- ranging from those groups whose members actually do the testing to other groups which directly represent consumers who are on the receiving end in terms of both diagnosis and paying the bills. We know that solutions to the problems I have described are essential.

The beauty of this legislation is that it resolves these problems. It protects both our health and our health care dollar. In reviewing this bill's predecessor -- S. 705 -- the Congressional Budget Office estimated that legislation such as this would actually save money -- up to \$37.07 million in the first year alone.

There is no reason for health care consumers or the federal government to tolerate incompetent performance in the laboratory. We believe that it is the clear responsibility of the federal government to work with the states and appropriate elements within the private sector to assure that reasonable and enforceable standards are adhered to by laboratories. We believe that CLIA of 1979 is the vehicle for such a program because it provides the basic framework necessary to assure that the public interest -- and indeed our lives -- are appropriately protected in the delivery of laboratory services.

Thank you for this opportunity to share our views with you. We would be happy to answer any questions the Committee may have.

NATIONAL COALITION FOR CLIA  
PARTICIPATING ORGANIZATIONS

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AMERICAN ASSOCIATION OF BIOANALYSTS  
AMERICAN ASSOCIATION FOR CLINICAL CHEMISTS  
AMERICAN CLINICAL LABORATORY ASSOCIATION  
AMERICAN MEDICAL TECHNOLOGISTS  
AMERICAN SOCIETY OF ELECTROENCEPHALOGRAPHIC TECHNOLOGISTS  
AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY  
AMERICAN SOCIETY FOR MICROBIOLOGY  
AMERICAN PUBLIC HEALTH ASSOCIATION  
ASSOCIATION OF INDEPENDENT COLLEGES AND SCHOOLS  
ASSOCIATION OF STATE AND TERRITORIAL HEALTH  
LABORATORY DIRECTORS  
EPILEPSY FOUNDATION OF AMERICA  
INTERNATIONAL SOCIETY OF CLINICAL TECHNOLOGISTS  
NATIONAL COALITION OF SPANISH MENTAL AND HUMAN  
SERVICES ORGANIZATIONS  
NATIONAL SOCIETY FOR HISTOTECHNOLOGY  
NATIONAL RETIRED TEACHERS/RETIRED PERSONS ASSOCIATION  
RURAL AMERICA  
U.S. CONFERENCE OF CITY HEALTH OFFICERS  
U. S. CONFERENCE OF MAYORS

Senator KENNEDY. Our next witness will be Dr. Weary who is speaking on behalf of the American Academy of Dermatology.

# STATEMENT OF PEYTON E. WEARY, M.D., AMERICAN ACADEMY OF DERMATOLOGY

Dr. WEARY. Thank you, Mr. Chairman.

I am Dr. Peyton Weary. I am chairman of the department of dermatology at the University of Virginia School of Medicine, and chairman of the Council on Governmental Liaison of the American Academy of Dermatology.

I may digress at times from the prepared testimony which I have submitted. First of all, I would like to say that we have been involved with the CLIA legislation on the House side and on the Senate side in the past. I am very pleased to note that one of our original concerns about the research laboratories exemption has been very adequately and appropriately addressed in this present legislation.

I would also like to digress to say that I believe the membership of the American Academy of Dermatology would strongly support the testimony that was given by the Department of Health, Education and Welfare in regard to exempting physician office laboratories until a further study is done.

But pending that, I would like to point out one of our very serious concerns about S. 590. In comparing S. 590 with its predecessor, S. 705, it is apparent that several very important portions of S. 705 were omitted from S. 590 which will have profound consequences.

I have noted these sections in the testimony. The precise language which was eliminated is as follows:

(D)(1) Upon such conditions as the Secretary may, by regulation, prescribe, the Secretary may, upon application, exempt from the national standards for clinical laboratories any clinical laboratory (I) which is located in the office of and operated by a licensed physician, dentist or podiatrist or a group of such practitioners, and (II) in which the only tests or procedures which are performed are tests or procedures performed by such a practitioner in connection with the treatment of his patients.

It is possible, I believe, that because of the similarity of these paragraphs and the following paragraphs in S. 705 that these statements were eliminated because they were thought to be redundant or repetitious.

They are not, in fact, redundant, and were inserted in S. 705 for a very specific and important purpose. The reason for their insertion was to permit physicians, dentists and podiatrists no matter what size group they may be affiliated with to perform laboratory procedures themselves on materials from their patients.

Elimination of these portions as is done in S. 590, means that under the proposed regulations physicians, dentists and podiatrists in groups of more than five are prohibited from performing personally a wide variety of simple but essential diagnostic office procedures for which they have had extensive training and experience, unless they apply to have their laboratories licensed and themselves designated as laboratory directors.

I would cite examples of such things, and I would like to demonstrate one, if I may. The dermatologist will often scrape the surface

of the skin and get some scales, to demonstrate the presence of fungal organisms.

I show you here an example of a ringworm. This is a fungus infection. Notice the similarity of the lesions to the lesions here of an entirely different disorder called pityriasis rosea. A clinician, even a skilled clinician could not look at such a lesion and say precisely that this one is a fungus infection or this one is the other condition.

However, we can simply scrape material from the surface, place it on a slide, apply a small amount of potassium hydroxide and gently heat it, and then in the fungus infection we can demonstrate these fungal organisms you see on this slide. This is an example of a simple procedure we do daily in our office. We do not charge the patients for it, it is a very cost-effective procedure, and it allows us to treat these conditions precisely.

Hematologists regularly examine the blood smear from their patients to determine the cellular morphology. They teach students that the physician who fails to do so when faced with certain types of anemia or blood disorders is remiss.

Allergists frequently examine nasal secretions or sputum for the presence of eosinophils, a special type of cell which would help to determine if the patient does, in fact, have allergic upper respiratory disease.

I have cited a number of other examples here—the internist who looks at material from cases of meningitis, obstetricians, and so forth—and I will not elaborate on these at the present time other than to say there are many such laboratory procedures which are performed either regularly or only occasionally. However, they are procedures which are simple and important and which allow the physician to treat the patient in a more effective way.

The American Academy of Dermatology feels certain that the Congress would not intentionally wish to interfere with the practice of medicine nor knowingly create obstacles to the performance of diagnostic procedures by trained physicians which would allow them to exercise their skills most effectively.

For this reason, we urge that 353(c)(D)(i)(I) and 353 (c)(D)(i)(II) of the Clinical Laboratory Improvement Act of 1977, S. 705, be reinstated in S. 590 with the following proviso.

It would seem entirely inappropriate to require physicians, dentists, or podiatrists to submit an application for exemption to perform laboratory procedures for which the individual is trained, and we have, therefore, changed the language slightly and this is submitted in the written testimony.

I would like now to turn to a second concern which the American Academy of Dermatology has. We have previously testified that we recognize the need for such legislation to eliminate the fraud and abuse potential of some of the unscrupulous laboratories and to assure proficiency and quality of tests in interstate laboratories, and in that sense we agree with the other panelists here at the table, although we are frankly somewhat skeptical of the reports from the CDC and the NBS that the problem of quality control is as severe as indicated.

We would assert, however, that while the Clinical Laboratory Improvement Act of 1979, S. 590, represents the culmination of 3



years of effort to eliminate many of the minor imperfections, this piece of legislation is still a classic example of costly regulatory overkill.

We would refer to the minority opinion expressed by Congressman James M. Collins of Texas in regard to the Clinical Laboratory Improvement Act of 1976, H.R. 14319, in which the following statement appears:

In short, this legislation goes to excessive lengths to correct perceived problems. The American people today want less government. They want less bureaucracy. Americans want lower taxes. We do not need this additional level of legal regulation.

The American Academy of Dermatology believes those sentiments are more widely accepted today as true than in 1976 when they were written and that they are applicable to S. 590 as they were to H.R. 14319.

We believe the major abuses, which prompted this proposed legislation, can be readily eliminated by a much less costly and administratively simpler bill which would:

One: Require conformity by those laboratories which are most suspect of fraud and abuse.

Two: Establish quality controls for the majority of laboratory procedures performed.

Three: Require proficiency testing for the majority of supervisory laboratory personnel and the majority of laboratory technical personnel in intrastate laboratories.

Four: Eliminate the virtually impossible task of requiring proficiency testing and quality controls for the multitude of less frequently performed procedures for which national standards could only be created at enormous cost and with extreme difficulty.

To accomplish this, we would propose:

One: That national standards, as called for in the bill, be required only for the 30 procedures most commonly ordered by physicians, dentists or podiatrists, and I have submitted the list of procedures which would be in this group. Actually, there are 35 on the list. We would suggest 30.

Two: That proficiency testing be required for those technical personnel who perform such procedures with the exception of those individuals exempted elsewhere in the bill.

Three: That credentials of supervisory personnel who oversee the performance of such procedures be subject to national standards in those laboratories which are exempted elsewhere in the bill.

Since the laboratories most subject to fraud and abuse are apt to be those which expend a majority of their effort in the performance of high-volume procedures, it would seem logical to conclude that these laboratories would come under the scrutiny of the regulatory agency and the quality of the 30 procedures for which they must be held accountable would provide a ready reference as to the overall proficiency of the supervisory and technical personnel.

For those laboratories which are not suspect in regard to fraud and abuse, the same quality controls would assure the overall laboratory proficiency.

This approach would be far less costly than one which requires development of national standards for possibly as many as 1,000 types of nonresearch laboratory procedures which may be per-

formed at hospital laboratories and other laboratories daily in this country.

To effect this change would require a very minimal alteration in the bill language and we have submitted the changes in the prepared testimony. We would suggest that the proposed limitation would be a truly cost-effective innovation and ultimately accomplish all that the legislation intends at a fraction of the cost.

We appreciate the opportunity to present this testimony to the subcommittee. Thank you, Mr. Chairman.

Senator KENNEDY. Dr. Weary, I think you heard read into the record some of the problems we are facing in terms of the Indian Health Service's inadequacy of the laboratories there.

You say in your testimony there really is not a need for this type of legislation, that the problem of quality control is not as severe as indicated. I am sure you are aware of the 1977 CDC study of 200 medicare laboratories which show serious deficiency, the HEW's forward plan of 1978 through 1982 which showed serious deficiencies.

I just ask you what your basis for drawing your conclusion is, based on the fact that serious studies done by various groups have reached conclusions quite to the contrary.

Dr. WEARY. Yes, Mr. Chairman, I am aware of those studies. I am also aware of the fact that in the 1967 study that was submitted by CDC, there were several members of the committee who were not at all satisfied that the report was accurate.

I would also call your attention to a report from the Massachusetts Medical Society, their synopsis and proceedings of the council meeting of May 18, 1977, in which there is an outline of a study that was done in the State of Massachusetts in which they were not able to duplicate nor to substantiate the findings of 8 to 25 percent inaccuracies.

[The following was received for the record:]

The Massachusetts Medical Society

RECEIVED

By \_\_\_\_\_

AUG 19 1977

NEED

PATHOLOGY

\_\_\_\_\_  
SYNOPSIS  
AND  
PROCEEDINGS  
OF THE  
COUNCIL MEETING  
May 18, 1977

\_\_\_\_\_  
PROCEEDINGS  
OF THE  
ANNUAL MEETING  
May 25, 1977

\_\_\_\_\_  
PROCEEDINGS OF THE ONE HUNDRED AND  
NINETY SIXTH ANNIVERSARY  
May 24 and 25, 1977

## PROCEEDINGS OF THE COUNCIL

### REPORT OF THE AD HOC COMMITTEE TO INVESTIGATE THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE 8-25% LABORATORY ERROR STATEMENT

#### A. PURPOSE

At its meeting of October 13, 1976, the Council of the Massachusetts Medical Society voted to refer a resolution calling for a study of certain laboratory procedures to committee. Such committee was to determine the applicability within the Commonwealth of a Department of Health, Education and Welfare allegation that 8-25% of laboratory tests are in error.

#### B. DEFINITION OF ERROR

Since any set of measurements is subject to analytical variation, the term "error" requires definition. The committee defines clinical laboratory error as a deviation from a true value of sufficient magnitude as to have the potential to mislead a physician with regard to diagnosis, management or therapy. Limits of such medically acceptable variation were determined for each procedure both by reference to the medical literature (1, 2, 3) and by informal clinician surveys conducted by members of the committee.

#### C. DATA SOURCES

1. Regional Quality Control Program of the Massachusetts Society of Pathologists (MSPRQCP). Approximately 170 laboratories within the Commonwealth participate.
2. Laboratory Improvement Program of the Massachusetts Department of Public Health (MLIP).
3. College of American Pathologists Proficiency Surveys (CAP Survey): Material from these surveys is national in scope with up to 8,000 laboratories participating. Since results for Massachusetts laboratories could not be extracted from the overall data, such data have inferential value only.
4. Center for Disease Control and Bureau of Biologics of the Food and Drug Administration. Nationwide survey material for hepatitis B antigen testing. As with the material from the College of American Pathologists Proficiency Surveys, results for Massachusetts laboratories could not be extracted from the overall data and such data, therefore, similarly has inferential value.

#### D. FINDINGS AND INTERPRETATIONS

##### 1. Hemoglobin

Medically acceptable variation:  $\pm 1.0$  g/dl. at 14 g/dl. level  $\pm 7\%$

##### MSPRQCP:

Mean 14.0 g/dl.

SD 0.25 g/dl.

Ave. CV 1.8%

##### CAP Survey (Set H-B 1976):

"True" mean (Cyanmethemoglobin)

11.1

"All methods" mean

10.9

Deviation

-0.2 g/dl.

(1.8%)

##### Interpretation

- (a) *Precision:* based on the MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 1% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of all methods from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for hemoglobin.

##### 2. Hematocrit

Medically acceptable variation:  $\pm 3.0$  hct. units at 44 hct. unit level ( $\pm 7\%$ )

**MSPRQCP:**

Mean 43.6 hct. units  
 SD 1.02 hct. units  
 Ave. CV 2.3%

**CAP Survey (Set H-B 1976):**

"True" value (microhematocrit) 32.6 hct. units  
 Mean "all methods" 33.9 hct. units  
 Deviation 1.3 hct. units (4%)

**Interpretation**

- (a) *Precision:* based on the MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 1% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of all methods from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for hematocrit.

**3. White Blood Count**

Medically acceptable variation:  $\pm 1000$  cells/cmm. at 7000 cells/cmm. level ( $\pm 14\%$ )

**MSPRQCP:**

Mean  $7.3 \times 10^3$ /cmm.  
 SD  $0.28 \times 10^3$ /cmm.  
 Ave. CV 3.8%

**CAP Survey (Set H-B 1976):**

"True" value (Coulter Particle Counter) 13.8  
 Mean all methods 13.4  
 Deviation -400 cells/cmm. (-2.9%)

**Interpretation**

- (a) *Precision:* based on the MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 1% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of "all methods" from the "true" mean to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for White Blood Count.

**4. Prothrombin Time**

Medically acceptable variation:  $\pm 1.5$  secs. at 12 sec. level ( $\pm 12\%$ )

**MSPRQCP:**

Mean 11.8 secs.  
 SD 0.43 secs.  
 Ave. CV 3.7%

**CAP Survey:**

"True" value (Fibrometer-Brain thromboplastin) 12.9  
 Mean of "all methods" 12.3  
 Deviation 0.6 secs. (4.7%)

**Interpretation**

- (a) *Precision:* based on the MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 1% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of "all methods" from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for Prothrombin Time.

## PROCEEDINGS OF THE COUNCIL

## 5. Platelets — No data available.

## 6. Glucose

Medically acceptable variation:  $\pm 10$  mg/dl. at 120mg/dl. level ( $\pm 8\%$ )

## MSPRQCP:

Mean 97 mg/dl.

SD 3.8 mg/dl.

Ave. CV 3.9%

## CAP Survey (Set C-D 1976):

"True" value (Hexokinase)

88.8 mg/dl.

Mean of "all methods"

85.5 mg/dl.

Deviation of mean from true value

-3.3 mg/dl.

(-3.7%)

## Interpretation

- (a) *Precision:* based on the MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 5% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of "all methods" from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for Glucose.

## 7. BUN

Medically acceptable variation:  $\pm 3$  mg/dl. at 25 mg/dl. ( $\pm 12\%$ )

## MSPRQCP:

Mean 19 mg/dl.

SD 1.0 mg/dl.

Ave. CV 5.5%

## CAP Survey (Set C-D 1976):

"True" value (Berthelot reaction)

49.9 mg/dl.

Mean of "all methods"

48.4 mg/dl.

Deviation of all methods from "true" value

-1.5 mg/dl.

(-3%)

## Interpretation

- (a) *Precision:* based on the MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 5% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of all methods from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for BUN.

## 8. Sodium

Medically acceptable variation:  $\pm 5$  mEq/l. at 140 mEq/l. level ( $\pm 3.5\%$ )

## MSPRQCP:

Mean 147 mEq/l.

SD 1.9 mEq/l.

Ave. CV 1.3%

## CAP SURVEY (Set C-D 1976):

"True" value (Flame emission photometry)

139.7 mEq/l.

Mean of "all methods"

139.8 mEq/l.

Deviation

0.1 mEq/l.

(0.07%)

## Interpretation

- (a) *Precision:* based on MSP data, the average participating laboratory deviates from its mean to a medically important degree less than 5% of the time.
- (b) *Accuracy:* CAP Survey results indicate the deviation of the mean of all methods from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for Sodium.

## 9. Potassium



MAY 18, 1977

Medically acceptable variation:  $\pm 0.2$  mEq/dl. at 4.5 mEq/l. level ( $\pm 4\%$ )**MSPRQCP:**

Mean 4.4 mEq/l.

SD 0.1 mEq/l.

Ave. CV 2.4%

CAP Survey (Set C-D 1976):

"True" value (Flame emission photometry) 6.00 mEq/l.

Mean of "all methods" 5.98 mEq/l.

Deviation 0.02 mEq/l.  
(3.3%)**Interpretation**

- (a) **Precision:** based on MSP data, the average participating laboratory deviates from its mean to a medically important degree about 5% of the time.
- (b) **Accuracy:** CAP Survey results indicate the deviation of the mean of all methods from the "true" mean value to be within acceptable limits.
- (c) The DHEW error rate allegation of 8-25% appears invalid for Potassium.

10. Blood pH — No published data available.

11. Blood PCO<sub>2</sub> — No published data available.12. Blood PO<sub>2</sub> — No published data available.**13. Hepatitis B Surface Antigen****Data Sources:** CAP Survey, Center for Disease Control and Bureau of Biologies of FDA, all 1976.**Results:** 97.5% correct responses**Interpretation**

The accuracy of testing for hepatitis B surface antigen by third generation tests shows an error rate below the 8-25% alleged by DHEW. It should be noted that third generation tests are required in the examination of all donor blood.

**14. Syphilis Serology****Results:** MLIP Survey, 1976 — 98.4% correct responses

CAP Series G 1976 — 96.7% correct responses

**Interpretation**

Data both for Massachusetts laboratories (MLIP) and national laboratories (CAP) reveals an error rate less than the 8-25% alleged by DHEW.

15. Anatomic Diagnosis of Cancer — No published data available.

16. Papanicolaou Smears — No published data available.

**17. Urine Culture****Data Source:** MLIP, 1976.

**Results:** Out of the 10 most frequent isolates from urine cultures accounting for over 90% to total urine isolates, the following 5 organisms were submitted to participating hospitals, designated as "urine cultures":

E. coli

K. pneumoniae

P. rettgeri

Enterobacter. cloacae

Staph. aureus

Agreement between participating and reference laboratories exceeded 95%. E. coli, in particular, which accounts for approximately 65% of all urine isolates, was identified correctly 97% of the time.

**Interpretation**

Massachusetts laboratories can identify the commonly encountered etiological agents of urinary tract infection with an error rate below the

## PROCEEDINGS OF THE COUNCIL

8-25% rate alleged by DHEW.

18. *Urine Colony Count* — No published data available.

19. *Blood Typing*

*Data Source:* MLIP, March 1975 and March, 1976.

*Results:* Agreement between participating and reference laboratories exceeded 99%.

20. *Compatibility Testing*

*Data Source:* MLIP, March 1976.

*Results:* Cross-match results of participating laboratories were in agreement with reference laboratory 100% of the time.

### *Interpretation*

The error rate for Massachusetts laboratories for blood typing and blood compatibility testing is below the 8-25% alleged by DHEW.

## E. RESULTS OF OPINION SURVEY OF MASSACHUSETTS MEDICAL SOCIETY COUNCILORS

113 councilors responded to a questionnaire submitted at the Council meeting of February 10, 1977. For thirteen of the tests listed, 96-100% of the responders disagreed with the DHEW allegations. For three of the tests, 90-95% disagreed and for four of the tests, 85-89% disagreed. The responding councilors are considered to be a representative sample of Massachusetts physicians. The majority of such physicians indicate that for the majority of tests specified, they believe the error rate is below the 8-25% level alleged by DHEW. It is of interest to note that the four tests assessed most poorly (85-89% disagreeing with DHEW) were hemoglobin, hematocrit, white cell count and platelet count. For platelet count no precision or accuracy data is available. For the other three tests, data is available and indicates a laboratory precision and accuracy within acceptable limits. (This poses a question regarding intra-individual variation for blood analytes limited exclusively to the vascular compartment. Discussion of this question is beyond the scope of this report.)

## F. GENERAL CONCLUSION

Reliable accuracy and precision data for those procedures where such data exist indicate that levels of accuracy and precision of Massachusetts laboratories are within medically useful limits. Based on such data, reinforced by the results of the survey of the councilors and the experience of the members of the Committee, it is the opinion of the Committee that the 8-25% error rate allegation by DHEW is not valid. The Committee cannot address those procedures for which no data is available and is of the opinion that any statements by DHEW regarding error rates for such procedures are inappropriate. It is furthermore the view of the Committee that the determination of acceptable limits of variation of testing in clinical laboratories is a medical decision which should be made appropriately by members of the physician community. Based on these conclusions, the Committee offers the following resolutions:

1. Resolved, that for the following procedures, viz:

- Blood typing
- Blood compatibility testing
- Syphilis serology
- Hepatitis-associated antigen (HB<sub>Ag</sub>)
- Serum potassium
- Serum sodium
- Blood or serum glucose
- Blood or serum urea nitrogen
- Hemoglobin
- Hematocrit
- White blood cell count
- Prothrombin time
- Urine culture



MAY 18, 1977

existing performance data for laboratories within the Commonwealth of Massachusetts indicate that error rates are below the 8-25% rate alleged by the Department of Health, Education and Welfare.

2. Resolved, that no threat to the public health and welfare of citizens within the Commonwealth exists on the basis of clinical laboratory performance.
3. Resolved, that the determination of medically acceptable limits of clinical laboratory variation is a medical judgment which should be made by the physician community.
4. Resolved, that this report be communicated to the Commissioner of Public Health, the Commonwealth and the Secretary of the Department of Health, Education and Welfare.

GEORGE F. KWASS, M.D., Chair  
BRADLEY E. COPELAND, M.D.  
DAVID M. MCGOLDRICK, M.D.

The next order of business was the presentation under suspension of the rules of the resolution of the Barnstable District to the effect that the Committee on Advocacy for Members in Socio-Economic Affairs be reappointed and continue its assigned activities. This was done by Frederick J. Duncan.

This was amended by vote to leave out the third "Executive Board" so that the end of the resolution would read: "of five members, chair and four members". The whole resolution, as amended, was then proved and appears below:

WHEREAS, the CAMSEA was established by the Council as a committee of advocacy for members in the socio-economic affairs and

WHEREAS, the CAMSEA was continued as a subcommittee of the Executive Board by the President approved by the Executive Board and the Council to pursue advocacy for members in socio-economic affairs and

WHEREAS, there is no other Medical Society committee charged with or pursuing such advocacy or charged with the planning and implementation of action programs for the achievement of physician socio-economic goals and

WHEREAS, the Executive Board of the Massachusetts Medical Society serves as a liaison committee between the Society and Blue Shield and Blue Cross and other third party carriers, and the CAMSEA, a subcommittee of the Executive Board has been performing this function and meeting regularly for the past two years on matters of socio-economic importance, reporting its recommendations to the Executive Board on deliberation and

WHEREAS, the charge to the CAMSEA has not yet been fulfilled despite diligent efforts, therefore, be it

RESOLVED: That the Council of the Massachusetts Medical Society direct the President to reappoint a CAMSEA a Subcommittee of the Executive Board subject to the approval of the Executive Board composed of five members (Chairman and four members)

That the Council of the Massachusetts Medical Society direct the CAMSEA to continue with planning, organizing and implementing appropriate action programs for the achievement of the socio-economic goals of the physicians subject to the approval of the Executive Board.

Under suspension of the rules, the following resolution from Haden was considered:

# MASSACHUSETTS MEDICAL SOCIETY

## Circular of Advanced Information for Councilors

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### JOINT MEETING OF THE COMMITTEE ON PUBLIC HEALTH AND THE SECTION ON PATHOLOGY

The meeting was called to order Friday, December 8, 1978 at the Harvard Club, 374 Commonwealth Avenue, Boston, by Nicholas Fiumara, Chairman of the Committee on Public Health. Dr. Bradley E. Copeland, representing Dr. A.W. Jones, Chairman of the Section on Pathology, was also in the chair.

Those invited included:

Mr. Stephen Tocco, Staff Assistant to Representative Edward Markey of Malden and the Seventh Congressional District;

Dr. George F. Grady, Director of the Bureau of Laboratories of the State Department of Public Health, Commonwealth of Massachusetts, representing Commissioner Jonathan Fielding;

Dr. Stuart Shapiro, representing Senator Edward Kennedy, sent word that he would be available for a meeting in the near future in Boston;

Mr. Joseph Califano, Secretary of the Department of Health, Education and Welfare, received the invitation, but had no comment;

Surgeon General Julius Richmond did not received the invitation, and it was forwarded to him.

In preparation for the meeting, the invited guests were sent a list of the medical laboratory tests currently paid for by Blue Shield of Massachusetts. Data secured from DHEW under the Freedom of Information Act was also included.

A specific proposal was made that if a particular test was identified as having an 8% or greater error rate, the Section on Pathology would start an immediate remedial program.

Mr. Tocco commented that in his conversation with the individuals in the Department of Health, Education and Welfare, it was mentioned that the laboratories in Massachusetts were of generally high calibre and that the nationwide need for regulatory legislation did not apply in Massachusetts. Mr. Tocco further stated that future national legislation would probably contain mechanisms for exemption by State from national laboratory regulation. He stated that although Massachusetts appears to be in a very good position for exemption, it would behoove the Medical Society and the State Department of Public Health to make a thorough evaluation of any problem areas so that when federal legislation was passed, Massachusetts would be ready to qualify for exemption.

Dr. Grady stated that if the Department of Health, Education and Welfare's statement is intended to mean that 8-25% of all medical laboratory tests done in Massachusetts are in error, he would not expect such a high error rate as described by the Department of Health, Education and Welfare. This is because the total number and variety of laboratory tests performed annually is weighted by a disproportionately large component of relatively simple procedures performed in larger laboratories that have a high degree of internal quality control. He also stated that he corroborated the low error rate in syphilis serology testing which

1 was pointed out in the report of the Ad Hoc Committee\* to Investigate the Department of  
2 Health, Education and Welfare Error Statement.

3 Dr. Grady also emphasized the in difficulty defining the word *error*, and the specific  
4 need for more specific definitions. He indicated that there were specific areas of laboratory  
5 testing for specific categories of laboratories in which there appeared to be a need for  
6 technical improvement. He emphasized the fact that different categories of laboratories ap-  
7 peared to have different problems. He offered assistance to the Medical Society and me. I con-  
8 ed the Clinical Laboratories Advisory Committee, Mr. John Norris, Esq., Chairman, and  
9 Ms. Nancy Ridley, Director of the Bureau of Laboratories Licensure and Certification, as in-  
10 dividuals who could also be very helpful in this effort.

11 The following principles were agreed upon by members of the Section on Pathology and  
12 the Committee on Public Health:

- 13 1. That any test that had a total error rate in excess of 8% was a threat to the public  
14 health of citizens of the Commonwealth;
- 15 2. That when such a test is defined, there should be immediate corrective action  
16 undertaken by the Section on Pathology. It is understood that error in this context  
17 means a test report which has an adverse effect on patient care.

18 It was pointed out by Dr. Fiumara that we were specifically addressing the statement of  
19 the Department of Health, Education and Welfare concerning the total error rate for the  
20 total number of laboratory tests. Dr. Fiumara indicated that he would expect the Section on  
21 Pathology to be in active communication with the Department of Health, Education and  
22 Welfare and Dr. Grady in order to identify any specific tests where improvement in  
23 laboratory testing is deemed necessary.

24 **RECOMMENDATION:** That the council approves the proposal that the section on  
25 Pathology Cooperate with the Department of Health, Education and Welfare and the  
26 Massachusetts State Department of Public Health to identify specific medical laboratory  
27 tests which need improvement and that the section on pathology should take steps to in-  
28 stitute remedial programs for the tests so identified.

29 \*of the Mass Medical Society

30 Submitted by A. W. Janes,  
31 Chairman, Section on Pathology

Matters to be considered  
at the stated meeting of the Council

**TIME:** Wednesday, February 14, 1979  
10:00 a.m.

**PLACE:** Howard Johnson 57 Hotel  
200 Stuart Street, Boston



Senator KENNEDY. That is good news for Massachusetts. But I do not know whether that is——

Dr. WEARY. We do not say there is not a need for legislation. We have always said that there is a need for it. What we are saying is that there is a better and less costly way to accomplish it and which would accomplish the same objectives.

Senator SCHWEIKER. You are not against having a clinical bill, are you?

Dr. WEARY. Not at all, Senator. In fact, we have not said that. We are skeptical of some of the 8 to 25 percent figures, but we are not against having legislation. We have not, at any time, testified in that regard.

Senator SCHWEIKER. As I understand, you support a bill, and a suggestion you make is that where a physician performs the test himself, that he be exempt from getting a license, is that correct?

Dr. WEARY. That is correct, sir.

Senator SCHWEIKER. And that is very similar to what we heard from HEW, or something close to that, in terms of a study and not to act at this point.

Dr. WEARY. Yes. They would also exempt all of physician office laboratories for the time being, and I would certainly support this, but I think even so, that where a physician has been trained and has the experience to do procedures, that physician under whatever bill is adopted should be allowed to pursue those procedures. This is what we are trained to do, Senator. I train my students to do these things.

Senator SCHWEIKER. Your exemption would not apply, as I understand it, if a medical technologist employed by the physician performed that test, is that correct or not?

Dr. WEARY. First of all, I do agree with the proposal from the administration that at least this be held in abeyance for the time being. It is reasonable to assume that possibly there may be a need to require some proficiency testing on the part of personnel who are employed by physicians in an office to do these tests, but I do think that until the information is available that it would be best to hold this in abeyance.

Senator SCHWEIKER. Now, the other point you are making is that if the bill is to focus on what I thought the purpose of the bill was which was medicaid fraud mills and storefront labs where I acknowledge the abuse and where obviously that is the part that has primarily been exposed and rightly so, that if we pick some 30 procedures, that this covers about 90 percent of the work that these kind of labs do, and that in all practical purposes, you are curing the problem without getting beyond some 30 or 35 procedures, is that correct?

Dr. WEARY. That is correct, Senator. It is very difficult for me in the short time allowed to get the data together, but I have reviewed the report on fraud and abuse prepared by the Select Committee on Aging, and in that report, they show one example of a storefront lab order sheet.

On that order sheet, there are 72 tests, and of the 72, 30 were in this group that I have proposed. I would venture to say that probably those 30 most commonly ordered tests account for probably 90 percent of the volume of that laboratory.

That laboratory could not exist without doing those 30 procedures I am quite convinced.

Senator SCHWEIKER. And how many tests or laboratory procedures would there be beyond the 30?

Dr. WEARY. If you are talking about nonresearch laboratory procedures, it is difficult. AAMC, I think, did a study a few years ago in which they got up to about 850 when they lost track of it.

Senator SCHWEIKER. The Association of American Medical Colleges said there are some 800?

Dr. WEARY. They have looked into this. I do not think that anybody at this point any idea exactly. I talked to my own laboratory people and they said, "Probably close to 1,000." But I have no cost idea at this point. You really have to go around the country and sample all the different hospitals and see what they are doing.

I would guess that a ballpark figure might be anywhere from 800 to 1,000 studies. We are not talking about research procedures now. We are talking about procedures that are done sometimes only once a month or once every 2 months, but they are done on patients or specimens from patients.

Senator SCHWEIKER. So your point is that by covering 90 percent you solve the basic fraud problem and we do not burden the Government with a lot regulation and procedure tests that maybe do not even apply except in a few cases, is that correct?

Dr. WEARY. That is quite correct, Senator. In fact, there are probably procedures being done right now in this country which may only be done in two or three laboratories in the United States or maybe one here and one in Sweden or somewhere.

There is no way that I could think that one could develop the national standards or quality proficiency testing for such infrequently done procedures where there is no national expert except in that laboratory or one or two laboratories that are doing it.

So how does one develop proficiency testing for these procedures? It would be an enormous and very costly process.

[The prepared statement of Dr. Weary follows:]

TESTIMONY OF  
PEYTON E. WEARY, M.D.  
ON BEHALF OF  
THE AMERICAN ACADEMY OF DERMATOLOGY  
IN REGARD TO  
THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979  
(S.590)  
SUBMITTED TO  
THE HEALTH SUBCOMMITTEE OF  
THE SENATE LABOR AND HUMAN RESOURCES COMMITTEE  
UNITED STATES SENATE  
MARCH 16, 1979

THE AMERICAN ACADEMY OF DERMATOLOGY, THE REPRESENTATIVE ORGANIZATION FOR OVER 90% OF THE APPROXIMATELY 5070 DERMATOLOGISTS IN THE UNITED STATES, IS PLEASED TO SUBMIT THE FOLLOWING TESTIMONY IN REGARD TO THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979 (S.590). TESTIMONY HAS BEEN PRESENTED BY THE ACADEMY ON SEVERAL OCCASIONS IN THE PAST BEFORE THE HEALTH SUBCOMMITTEE OF THE HOUSE ON H.R. 11341, THE COMPANION LEGISLATION TO S. 705, THE PREDECESSOR OF S.590 AND DURING THE DELIBERATIONS ON S.705 DISCUSSIONS WITH MEMBERS OF THE SENATE SUBCOMMITTEE STAFF ABOUT S.705 WERE INITIATED BY THE ACADEMY.

THE AMERICAN ACADEMY OF DERMATOLOGY WISHES TO EXPRESS ITS SERIOUS CONCERN ABOUT S.590 AS FOLLOWS:

- I. IN COMPARING S.590 WITH ITS PREDECESSOR S.705, IT IS APPARENT THAT SEVERAL VERY IMPORTANT PORTIONS OF S.705 WERE OMITTED FROM S.590 WHICH WILL HAVE PROFOUND CONSEQUENCES. THE PORTIONS ELIMINATED FROM S.705 ARE:

SECTION 353 (c) (D) (i) (I) AND

SECTION 353 (c) (D) (i) (II)

THE PRECISE LANGUAGE ELIMINATED IS AS FOLLOWS:

"(D) (i) UPON SUCH CONDITIONS AS THE SECRETARY MAY BY REGULATION PRESCRIBE, THE SECRETARY MAY UPON APPLICATION, EXEMPT FROM THE NATIONAL STANDARDS FOR CLINICAL LABORATORIES ANY CLINICAL LABORATORY -

"(I) WHICH IS LOCATED IN THE OFFICE OF, AND OPERATED BY, A LICENSED PHYSICIAN, DENTIST OR PODIATRIST, OR A GROUP OF SUCH PRACTITIONERS, AND "(II) IN WHICH THE ONLY TESTS OR PROCEDURES WHICH ARE PERFORMED ARE TESTS OR PROCEDURES PERFORMED BY SUCH A PRACTITIONER IN CONNECTION WITH THE TREATMENT OF HIS PATIENTS."



BECAUSE OF THE SIMILARITY WITH THE PARAGRAPHS FOLLOWING SECTION 353 (c) (D) (ii) (I) AND SECTION 353 (c) (D) (ii) (II) IT IS POSSIBLE THAT THESE STATEMENTS WERE ELIMINATED BECAUSE THEY WERE FELT TO BE REDUNDANT OR REPETITIOUS. THEY ARE NOT, IN FACT, REDUNDANT AND WERE INSERTED IN S.705 FOR A VERY SPECIFIC AND IMPORTANT PURPOSE. THE REASON FOR THEIR INSERTION WAS TO PERMIT PHYSICIANS, DENTISTS AND PODIATRISTS, NO MATTER WHAT SIZE GROUP THEY MAY BE AFFILIATED WITH, TO PERFORM LABORATORY PROCEDURES THEMSELVES ON MATERIALS FROM THEIR PATIENTS. THE ELIMINATION OF THESE PORTIONS AS IN S.590 MEANS THAT UNDER THE PROPOSED REGULATIONS PHYSICIANS, DENTISTS AND PODIATRISTS IN GROUPS OF MORE THAN FIVE ARE PROHIBITED FROM PERFORMING PERSONALLY A WIDE VARIETY OF SIMPLE BUT ESSENTIAL DIAGNOSTIC OFFICE LABORATORY PROCEDURES FOR WHICH THEY HAVE HAD EXTENSIVE TRAINING AND EXPERIENCE UNLESS THEY APPLY TO HAVE THEIR LABORATORIES LICENSED AND THEMSELVES DESIGNATED AS LABORATORY DIRECTORS. WE WOULD CITE AS EXAMPLES OF SUCH SIMPLE BUT IMPORTANT LABORATORY PROCEDURES THE FOLLOWING:

1. DERMATOLOGISTS OFTEN SCRAPE THE SCALE FROM THE SURFACE OF SKIN LESIONS SUSPECTED OF BEING FUNGAL IN NATURE. THESE SCALES, WITH A MINIMUM OF PREPARATION, ARE EXAMINED UNDER THE MICROSCOPE TO DETECT THE FUNGAL ORGANISMS. ALL DERMATOLOGISTS AND MANY NON-DERMATOLOGIST PHYSICIANS ARE TRAINED TO DO THIS SIMPLE PROCEDURE WHICH ALLOWS PRECISE IDENTIFICATION OF THE LESION AS FUNGAL AND THUS THE USE OF APPROPRIATE TREATMENT.
2. HEMATOLOGISTS REGULARLY EXAMINE THE BLOOD SMEAR FROM THEIR PATIENTS TO DETERMINE THE CELLULAR MORPHOLOGY. THEY TEACH STUDENTS THAT THE PHYSICIAN WHO FAILS TO DO SO WHEN FACED WITH CERTAIN TYPES OF ANEMIA OR BLOOD DISORDERS IS REMISS.



3. ALLERGISTS FREQUENTLY EXAMINE NASAL SECRETIONS OR SPUTUM FOR THE PRESENCE OF EOSINOPHILS, A SPECIAL TYPE OF CELL, WHICH WOULD HELP TO DETERMINE IF THE PATIENT DOES, IN FACT, HAVE ALLERGIC UPPER RESPIRATORY DISEASE.
4. INTERNISTS AND PEDIATRICIANS INVARIABLY EXAMINE CEREBROSPINAL FLUID IMMEDIATELY AFTER WITHDRAWAL TO DETERMINE THE PRESENCE OF BACTERIAL OR YEAST ORGANISMS IN SUSPECTED CASES OF MENINGITIS.
5. OBSTETRICIANS REGULARLY EXAMINE VAGINAL SECRETIONS FOR THE PRESENCE OF YEAST ORGANISMS (CANDIDA ALBICANS) OR TRICHOMONAS ORGANISMS IN PATIENTS WITH VAGINITIS OR VAGINAL DISCHARGE.
6. CARDIOLOGISTS OFTEN PERSONALLY PERFORM ELECTROCARDIOGRAMS ON THEIR PATIENTS. ONE MUST ASSUME THAT SINCE BIOPHYSICAL LABORATORY PROCEDURES ARE MENTIONED IN THE DEFINITION OF A CLINICAL LABORATORY, THE ELECTROCARDIOGRAM IS INCLUDED.
7. THERE ARE MANY OTHER EXAMINATIONS, SOME PERFORMED REGULARLY, OTHERS OCCASIONALLY BY PHYSICIANS THEMSELVES ON BODILY SECRETIONS OR EXCRETIONS WHICH THE PHYSICIAN CANNOT OR WILL NOT ENTRUST TO A ROUTINE CLINICAL LABORATORY.

THE AMERICAN ACADEMY OF DERMATOLOGY FEELS CERTAIN THAT THE CONGRESS WOULD NOT INTENTIONALLY WISH TO INTERFERE WITH THE PRACTICE OF MEDICINE NOR KNOWINGLY CREATE OBSTACLES TO THE PERFORMANCE OF DIAGNOSTIC MANEUVERS BY TRAINED PHYSICIANS WHICH WOULD ALLOW THEM TO EXERCISE THEIR SKILLS MOST EFFECTIVELY. FOR THIS REASON WE URGE THAT SECTION 333 (c) (2) (4) (I) AND SECTION 333 (c) (2) (4) (II) OF THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1977 (S.705) BE REINSTATED IN S.590 WITH THE FOLLOWING PROVISIO. IT WOULD SEEM ENTIRELY INAPPROPRIATE TO REQUIRE A PHYSICIAN, DENTIST OR PODIATRIST TO SUBMIT AN APPLICATION FOR

EXEMPTION TO PERFORM LABORATORY PROCEDURES FOR WHICH THE INDIVIDUAL IS TRAINED. WE WOULD, THEREFORE, SUGGEST THE FOLLOWING ADDITIONS TO THE LANGUAGE OF 5.590 (UNDERLINED BELOW):

SECTION 372 (f)

"(3) (A) UPON SUCH CONDITIONS AS THE SECRETARY MAY BY REGULATIONS PRESCRIBE, THE SECRETARY SHALL EXEMPT FROM THE NATIONAL STANDARDS FOR CLINICAL LABORATORIES ANY LABORATORY -

(i) WHICH IS LOCATED IN THE OFFICE OF, AND OPERATED BY A LICENSED PHYSICIAN, DENTIST OR PODIATRIST OR A GROUP OF SUCH PRACTITIONERS, AND

(ii) IN WHICH THE ONLY TESTS OR PROCEDURES WHICH ARE PERFORMED ARE TESTS OR PROCEDURES PERFORMED BY SUCH A PRACTITIONER IN CONNECTION WITH THE TREATMENT OF HIS PATIENTS.

PRESENT  
(3) (A)

"(B) UPON SUCH CONDITIONS AS THE SECRETARY MAY BY REGULATION PRESCRIBE, THE SECRETARY MAY EXEMPT FROM THE NATIONAL STANDARDS FOR CLINICAL LABORATORIES ANY CLINICAL LABORATORY ---

(i) ETC.

II. THE AMERICAN ACADEMY OF DERMATOLOGY HAS PREVIOUSLY TESTIFIED THAT IT RECOGNIZES A NEED FOR SOME LEGISLATION TO ELIMINATE THE FRAUD AND ABUSE POTENTIAL OF SOME UNSCRUPULOUS LABORATORIES, AND TO ASSURE PROFICIENCY AND QUALITY OF TESTS IN INTRASTATE LABORATORIES, ALTHOUGH WE ARE FRANKLY SKEPTICAL OF REPORTS FROM

THE C.D.C. AND THE N.B.S. THAT THE PROBLEM OF QUALITY CONTROL IS AS SEVERE AS INDICATED. WE WOULD ASSERT, HOWEVER, THAT, WHILE THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979 (S.590) REPRESENTS THE CULMINATION OF THREE YEARS OF EFFORT TO ELIMINATE MANY OF THE MINOR IMPERFECTIONS, THIS PIECE OF LEGISLATION IS STILL A CLASSIC EXAMPLE OF COSTLY REGULATORY OVERKILL. WE WOULD REFER TO THE MINORITY OPINION EXPRESSED BY CONGRESSMAN JAMES M. COLLINS OF TEXAS IN REGARD TO THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1976 (H.R. 14319) IN WHICH THE FOLLOWING STATEMENT APPEARS: "IN SHORT THIS LEGISLATION GOES TO EXCESSIVE LENGTHS TO CORRECT PERCEIVED PROBLEMS. THE AMERICAN PEOPLE TODAY WANT LESS GOVERNMENT. THEY WANT LESS BUREAUCRACY. AMERICANS WANT LOWER TAXES. WE DO NOT NEED THIS ADDITIONAL LEVEL OF LEGAL REGULATION." THE AMERICAN ACADEMY OF DERMATOLOGY BELIEVES THOSE SENTIMENTS ARE MORE WIDELY ACCEPTED TODAY AS TRUE THAN IN 1976 WHEN THEY WERE WRITTEN AND THAT THEY ARE AS APPLICABLE TO S.590 AS THEY WERE TO H.R. 14319. WE BELIEVE THE MAJOR ABUSES WHICH PROMPTED THIS PROPOSED LEGISLATION CAN BE READILY ELIMINATED BY A MUCH LESS COSTLY AND ADMINISTRATIVELY SIMPLER BILL WHICH WOULD:

1. REQUIRE CONFORMITY BY THOSE LABORATORIES WHICH ARE MOST SUSPECT OF FRAUD AND ABUSE.
2. ESTABLISH QUALITY CONTROLS FOR THE MAJORITY OF LABORATORY PROCEDURES PERFORMED.
3. REQUIRE PROFICIENCY TESTING FOR THE MAJORITY OF SUPERVISORY LABORATORY PERSONNEL AND THE MAJORITY OF LABORATORY TECHNICAL PERSONNEL IN INTRASTATE LABORATORIES.
4. ELIMINATE THE VIRTUALLY IMPOSSIBLE TASK OF REQUIRING PROFICIENCY TESTING AND QUALITY CONTROLS FOR THE MULTITUDE

OF LESS FREQUENTLY PERFORMED PROCEDURES FOR WHICH NATIONAL STANDARDS COULD ONLY BE CREATED AT ENORMOUS COST AND WITH EXTREME DIFFICULTY.

TO ACCOMPLISH THIS WE WOULD PROPOSE THAT:

1. NATIONAL STANDARDS AS CALLED FOR IN THE BILL, BE REQUIRED ONLY FOR THE 30 PROCEDURES MOST COMMONLY ORDERED BY PHYSICIANS, DENTISTS OR PODIATRISTS (SEE APPENDIX A).
2. THAT PROFICIENCY TESTING BE REQUIRED FOR THOSE TECHNICAL PERSONNEL WHO PERFORM SUCH PROCEDURES WITH THE EXCEPTION OF THOSE INDIVIDUALS EXEMPTED ELSEWHERE IN THE BILL.
3. THAT CREDENTIALS OF SUPERVISORY PERSONNEL WHO OVERSEE THE PERFORMANCE OF SUCH PROCEDURES BE SUBJECT TO NATIONAL STANDARDS IN THOSE LABORATORIES WHICH ARE NOT EXEMPTED ELSEWHERE IN THE BILL.

SINCE THE LABORATORIES MOST SUBJECT TO FRAUD AND ABUSE ARE APT TO BE THOSE WHICH EXPEND A MAJORITY OF THEIR EFFORT IN THE PERFORMANCE OF HIGH VOLUME PROCEDURES, IT WOULD SEEM LOGICAL TO CONCLUDE THAT THESE LABORATORIES WOULD COME UNDER THE SCRUTINY OF THE REGULATORY AGENCY AND THE QUALITY OF THE 30 PROCEDURES FOR WHICH THEY MUST BE HELD ACCOUNTABLE WOULD PROVIDE A READY REFERENCE AS TO THE OVERALL PROFICIENCY OF THEIR SUPERVISORY AND TECHNICAL PERSONNEL.

FOR THOSE LABORATORIES WHICH ARE NOT SUSPECT IN REGARD TO FRAUD AND ABUSE, THE SAME QUALITY CONTROLS WOULD ASSURE THE OVERALL LABORATORY PROFICIENCY.

THIS APPROACH WOULD BE FAR LESS COSTLY THAN ONE WHICH REQUIRES DEVELOPMENT OF NATIONAL STANDARDS FOR THE OVER 1000 TYPES OF NON-RESEARCH LABORATORY PROCEDURES WHICH ARE PERFORMED BY HOSPITAL

LABORATORIES AND OTHER LABORATORIES DAILY IN THIS COUNTRY.

TO EFFECT THIS CHANGE WOULD REQUIRE VERY MINIMAL ALTERATION  
IN THE BILL LANGUAGE AS FOLLOWS (ADDITIONAL LANGUAGE UNDERLINED):

'NATIONAL STANDARDS

"SEC. 372. (a) WITHIN ONE YEAR AFTER THE DATE OF  
ENACTMENT OF THE CLINICAL LABORATORY IMPROVEMENT  
ACT OF 1979, THE SECRETARY SHALL PUBLISH PROPOSED  
NATIONAL STANDARDS FOR THE 30 MOST COMMONLY ORDERED  
LABORATORY PROCEDURES AMONG THOSE IDENTIFIED IN  
SECTION 370 (1) (A) AND FOR THE CLINICAL LABORATORIES  
WHICH PERFORM THESE 30 PROCEDURES. WITHIN 180 DAYS AFTER  
SUCH STANDARDS ARE PROPOSED, THE SECRETARY SHALL PROMULGATE  
SUCH STANDARDS WITH SUCH MODIFICATIONS AS THE SECRETARY DEEMS  
APPROPRIATE AND SUCH STANDARDS SHALL TAKE EFFECT UPON THEIR  
PROMULGATION. STANDARDS UNDER THIS SUBSECTION MAY BE AMENDED  
BY THE SECRETARY.

WE WOULD SUGGEST THAT THE PROPOSED LIMITATION WOULD BE A TRULY  
COST-EFFECTIVE INNOVATION, AND ULTIMATELY ACCOMPLISH ALL THAT THE  
LEGISLATION INTENDS AT A FRACTION OF THE COST. WE APPRECIATE THE  
OPPORTUNITY TO PRESENT THIS TESTIMONY TO THIS SUBCOMMITTEE.

Senator KENNEDY. Senator Javits?

Senator JAVITS. Thank you very much.

I would like to thank the witnesses and Dr. Weary for their testimony.

Dr. Wilder, the National Coalition for CLIA has many participating organizations. I notice the list attached to your testimony including the American Public Health Association, the National Retired Teachers, the Retired Persons Association, the U.S. Conference of Mayors.

May we introduce that whole list into the record?

Dr. WILDER. Yes, sir.

Senator JAVITS. And I ask unanimous consent of the Chairman.

Senator KENNEDY. Without objection.

[The following was received for the record:]

#### NATIONAL COALITION FOR CLIA PARTICIPATING ORGANIZATIONS

American Association of Bioanalysts.

American Association for Clinical Chemists.

American Clinical Laboratory Association.

American Medical Technologists.

American Society of Electroencephalographic Technologists.

American Society for Medical Technology.

American Society for Microbiology.

American Public Health Association.

Association of Independent Colleges and Schools.

Association of State and Territorial Health Laboratory Directors.

Epilepsy Foundation of America.

International Society of Clinical Technologists.

National Coalition of Spanish Mental and Human Services Organizations.

National Society for Histotechnology.

National Retired Teachers/Retired Persons Association.

Rural America.

U.S. Conference of City Health Officers.

U.S. Conference of Mayors.

Senator JAVITS. Now, do you find anything in this bill, Dr. Wilder, which mandates the development of licensure standards, insofar as particular tests are concerned, by HEW?

Dr. WILDER. No, sir.

Senator JAVITS. In other words, we ask them to develop standards, but they have the discretion as to what particular tests they will cover; is that correct?

Dr. WILDER. Yes, sir.

Senator JAVITS. I might say, as the author of this bill, that that is my purpose. I have no desire to mandate covering every one of 800 or 1,000 tests, but solely those which they believe should be and can be practically covered.

Dr. WILDER. I think our major concern is improved health care. There are enough examples of disasters occurring from improper laboratory data that this needs to be addressed.

Senator JAVITS. Now, Ms. Davis, you teach, I gather; associate professor of clinical laboratory sciences. I gather you teach or have supervision over the teaching of this subject.

Ms. DAVIS. Yes, sir.

Senator JAVITS. And how long have you been doing this?

Ms. DAVIS. Over 20 years.

Senator JAVITS. And you are the secretary of the American Society for Medical Technology?

Ms. DAVIS. Yes, sir.

Senator JAVITS. So you are an official of that organization?

Ms. DAVIS. Yes, sir.

Senator JAVITS. Now, what do you think about the practicality in this particular profession of picking out 30 or 35 tests and endeavoring to administer this kind of law on that basis?

Ms. DAVIS. I do not think it has ever been in the intent of the various CLIA's that we have had to do that. Actually, quality control is as much a philosophy as it is a series of techniques, and you just do not turn it off and on like a water faucet.

Most quality control methodologies and techniques are for many, many procedures more than 30 for which standards do exist, and there is no question of the need for it, for those esoteric procedures that are only done in a few places in the world. There are no standards that could reasonably be used, but those are very rare instances.

The state of the art, as far as the technology of quality control, is very good if people would only use it.

Senator JAVITS. So you feel that, practically, such a technique could not be administered?

Ms. DAVIS. Well, I think that the effect, functional effect of that would occur, but what I am saying is it would not be necessary to pick out 30 tests and name them specifically.

Senator JAVITS. Can that be done practically with laboratories? Can you operate that way?

Ms. DAVIS. I think it would be very difficult.

Senator JAVITS. Now, one of the things that you would know about as a teacher of this subject, experienced in the laboratory, is how far the interagency agreement which HEW says it has now concluded is taking us in terms of different standards, that is, different standards for different agencies; the Federal Government, for example, in medicare and medicaid; the Center for Disease Control, et cetera.

How many agencies are actually in this field and have separate sets of standards?

Ms. DAVIS. Well, there are at least three that we know of. You have got CLIA 1967 enforcement which, at one time, was primarily the responsibility of CDC. Then you have the medicare, which is the responsibility of HCFA.

Then you had the blood banks, particularly those licensed for interstate commerce that have been the responsibility of FDA. I think the interagency agreement is probably a good faith attempt to try to coordinate this.

Certainly one of the results after 5 years, 4 or 5 years, has been to cut down on the number of inspections, but that does not solve the problem of the still disparate groups of regulations that exist because we have disparate pieces of legislation.

And what we look to CLIA to do is actually cut down on the present situation which is regulatory overkill. We are now trying to deal with three different sets of very different, conflicting regulations, and we are unable to do it.

And no matter how hard HEW tries to do that, and I think they have, they are still faced with the constraints because the legisla-

tion exists. If CLIA can unify this, then not only will we have just one inspector going in, we will have one set of regulations.

Senator JAVITS. For example, if an inspector comes into a laboratory, he has three separate sets of regulations that he has to administer, is that correct?

Ms. DAVIS. Yes. It is very confusing to the people in the laboratory who are trying to comply with these regulations. But in talking to our people in the State agency, in the State of Tennessee, they are confused, too. They finally had to put together a special kind of checklist to use so they are not juggling three different pieces of paper as they go into the lab.

Senator JAVITS. They put that together themselves?

Ms. DAVIS. Themselves, yes.

Senator JAVITS. We had an estimate from the Congressional Budget Office last year that this bill would save \$37 million the first year.

How does this bill save money?

Ms. DAVIS. I think it has to do with some of the provisions for elimination of freedom of choice in the medicare reimbursement mechanisms. I think it is primarily in the area of medicare reimbursement.

Also in the present version of CLIA, since you have eliminated the Advisory Council and some things like that, it does become less costly. I think the Congressional Budget Office also, when they reviewed CLIA 1978, the House version, took that a little bit further and said that there might be \$126 million savings over a 5-year period, and they thought that was a conservative estimate.

Senator JAVITS. So that this would economize rather than the other way.

Ms. DAVIS. Right. That is net saved.

Senator JAVITS. And you do not consider this a regulatory bill. It really is an effort to rationalize the regulatory.

Ms. DAVIS. And unify and cutout this crazy quilt that exists now.

Senator JAVITS. Dr. Hausler, as director of the Iowa Hygienic Laboratories, which I gather operates a voluntary program of proficiency testing under contract to the Center for Disease Control, could we have your opinion of the bill, what there is in the way of a real need for this bill today?

Dr. HAUSLER. Senator Javits, I believe that the first thing that it helps us with is developing national standards, as Ms. Davis has spoken to. As she says, there are three areas, but there is also a fourth one in some of the States having their own laboratory standards. So we have actually four rather than three.

I see this legislation helping us greatly in establishing those national standards for personnel. It also assists us in providing some level of laboratory performance, something akin to the primary, secondary and tertiary facilities or hospital that we could see developed—the laboratories themselves developing into the levels of ability according to the practice community that they are serving.

And finally, the important aspect of this is the fact that it truly is an improvement legislation. The appropriation is to assist in the—for technical and consultative services in the State, and that clearly is the support of the voluntary program that we operate,



both a voluntary proficiency testing program and a voluntary continuing education program.

And you must remember that in any voluntary program, P.T. or anything else, it is only the most conscientious laboratory that participates and the performance of these volunteer labs is, in many instances, the best that they can do. So it would certainly help us in that regard.

Senator JAVITS. I have especially provided in the legislation that proficiency testing may be at the choice of the laboratory in question. There are many, I gather, organizations fully qualified to do proficiency testing including professional organizations; that is, organizations of the profession itself?

Dr. HAUSLER. That is correct, sir. The important thing is external audit.

Senator JAVITS. Well, I wish it to be noted that the bill leaves freedom of choice.

Dr. HAUSLER. That is correct.

Senator JAVITS. One last point. Your State does not have a State regulatory law respecting the matter. You heard HEW suggest that we should not seek to bring under this bill a State and local governmentally sponsored laboratory. What do you think of that?

Dr. HAUSLER. I think that all laboratories should be involved whether they are State level, local governmental level or what it may be. It is the patient that is being served. It is the consumer that is being served, and all of them demand the same quality of care and service.

Senator JAVITS. You do not think that we are made secure by the fact that the States have an interest in their citizens just like the Federal Government. Why do you not feel that States are just as interested as we are in looking at it?

Dr. HAUSLER. Well, political systems in the States in some instances would negate that or work against it. I know in my own State we utilize voluntarily in my laboratory, the inspection program, the inspection reports, the system and so forth. But without a mandate, there is no need to do that, and many laboratories would opt to go the easier route.

Senator JAVITS. So you feel that we should keep our provisions with respect to the State overlapping?

Dr. HAUSLER. My opinion is that we should include all laboratories.

Senator JAVITS. Now, Ms. O'Reilly, turning to you. What is your interest in this legislation? Tell us anything you wish to tell us about consumer protection aspects.

Ms. O'REILLY. Thank you, Senator.

As you know, Consumer Federation of America is a federation of some 220 national, State and local organizations including 60 State and local consumer groups in 47 States. We have the National Council of Senior Citizens, American Association of Retired Persons, Consumers Union, 16 national labor unions, some 90 credit and cooperative organizations, National Council of Jewish Women, and the YWCA. That spectrum of organizations for the third year in a row has just recently passed a policy resolution unanimously urging passage of legislation encompassing the principles of your bill.

Consumers really have a twofold stake. The most obvious one is one of humanness. The case catalogs of the true human tragedy which can and does result from errors in laboratory testing are the kinds of dimensions that cannot be ignored—undiagnosed diabetes, unnecessary hysterectomies, deaths that are really avoidable if there had been earlier accurate detection.

But equally compelling is the sheer economic dimension of this whole picture. The \$12 billion a year that consumers spent on laboratory testing and the very fact, as you have indicated and Senator Kennedy has indicated, that cost savings to the Government in the medicare and the medicaid field alone is most impressive.

I think that our enthusiasm for this bill is sharpened by the fact that it does include private physician labs. We sharply disagree with the HEW approach. When they presented that years ago, we were mystified by that recommendation.

Now, frankly, we are sheerly impatient with that recommendation, because any suggestions that we need a study to determine whether there is a problem with physician labs ignores the fact that there five studies, at least, that have already demonstrated most persuasively that are serious problems with private physician labs, and the extension of another year really is senseless.

As a matter of managerial efficiency it makes sense to include all of the dimensions of the laboratory testing, the independents, the hospitals and the private physician labs.

So our interest is keen as I say both from the humaneness and the economic considerations.

Senator JAVITS. Thank you. I might say that our estimate is only a ballpark estimate and it is rather that a quarter of all of the laboratory tests are done in physicians' offices, but we will ask the HEW to give us an opinion.

Ms. DAVIS. The Daymen Corp., Senator, has done a study that shows that it is in the neighborhood of 25 percent which, if anything, really understates the situation, because a large number of the tests that the independent laboratories conduct, those specimens are collected by the private physician.

Also, the large number of the hospital tests is also a distortion in light of the fact that so many of the hospital testing is in the monitor not just the diagnostic state.

Senator JAVITS. Thank you very much.

Dr. Weary, I have one point I would like to make with you. I would appreciate it if you would help me.

I ask unanimous consent that section 370 in parens be made part of the record, which defines the term "laboratory" and "clinical laboratory," Mr. Chairman.

Senator KENNEDY. Without objection.

[The following was received for the record:]

[Excerpt from Senate Bill S. 590, Sec. 370, Pp. 3-4]

## “PART H—CLINICAL LABORATORIES

### “DEFINITIONS

“SEC. 370. As used in this part—

“(1) The terms ‘laboratory’ and ‘clinical laboratory’ mean (A) a facility for the biological, microbiological, serological, chemical, immunohematological, radioimmunological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, humans, or (B) a facility for the collection, processing, and transmission of such materials for such purposes, other than a facility exclusively engaged in the collection or processing of human blood or its components intended for transfusion or further manufacturing.

“(2) The term ‘interstate commerce’ means trade, traffic, commerce, transportation, transmission, or communication between any State, territory, or possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

Senator JAVITS. Doctor, would you examine that carefully because we have looked over the seven procedures which you refer to as being, quote, in your statement, "We would cite as examples of such simple but important laboratory procedures the following:", end of quote.

Now, we have gone over those with my assistant and remember we are not professionals, and that is why I am asking you to do it. We have gone over each of these, and we do not believe that they, the seventh being a generalized, you know, there are many other examples, but the six, we believe are diagnostic procedures, not laboratory procedures.

So may we suggest to you that you examine your example and look at our definition, and if you have a suggestion for the definition which would make it clear that we do not have in mind or see to cover the diagnostic procedures of the doctor, like yourself, and make any suggestions that you would care to to us about the definition, because we do not think that your objection matches the definition, would you be good enough?

Dr. WEARY. Senator Javits, these are materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease.

The vaginal secretions of a woman are materials derived from the human body. The blood from the—which the hematologist looks at, the cerebral spinal fluid which he withdraws and looks for bacteria for meningitis, the scales from the skin, the sputum from the individual which the allergist looks for for eosinophils are all materials derived from the human body for purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of or the assessment of the health of humans. These are all materials.

Senator JAVITS. I asked you to make any suggestions.

Dr. WEARY. So what we would propose is that when the physician himself or a dentist or a podiatrist examines these materials and does a procedure which he has received training for in medical school—which I train my students and my residents to do—that he should be allowed to do that without having to qualify himself as a laboratory director and to apply for license. It just does not make any sense to do that.

Senator JAVITS. Doctor, we are passing each other in the night. I am telling you that we are not reaching that at all and we do not intend to. We only intend to reach the doctor who tests your urine for sugar, to make it simple.

Therefore, I say to you, if you can make any suggestion that you would like to respecting the definition which would make it clear that we do not include the doctor's diagnostic work which is what you are talking about.

But if you cannot do it or do not——

Dr. WEARY. Yes, we will be glad to work on the definition if you wish.

Senator JAVITS. Thank you so much.

[The following material was subsequently received for the the record:]



*AMERICAN ACADEMY of DERMATOLOGY, Inc.*

COUNCIL ON GOVERNMENTAL LIAISON  
Office of the Chairman

March 19, 1979

The Honorable Jacob K. Javits  
321 Russell Senate Office Building  
Washington, D.C. 20510

Dear Senator Javits:

I appreciated very much the opportunity to testify before the Senate Health Subcommittee on March 16 on behalf of the American Academy of Dermatology in regard to the Clinical Laboratories Improvement Act of 1979. I would again reiterate my comment that the Academy endorses the intent of the legislation and the need for some legislation but feels strongly that the legislation should be carefully tailored to correct the problem with the least amount of regulation and in the most cost-effective manner. It was to this end that the recommendation to limit the scope of the legislation to the 30 most commonly ordered tests was made, and we would still contend that this would be a practical and far less costly method than any other proposed.

You have requested that I prepare a revision of the definition of a clinical laboratory as presented in Section 370 which would address the issues I raised in my testimony. I welcome the opportunity to do so because it is, in fact, the enormous scope of the definition which requires such a massive regulatory response. I have quite frankly sought to limit the scope of the definition in ways which will not impair the basic intent of the legislation but will define on a more rational basis precisely those areas for which regulatory authority will be sought. Because definitions by their very nature require exclusions I have added several of the exemptions now comprising Section 372 (3) (A) and 372 (3) (D) to the original definition Section 370 where I believe it more appropriate for them to be since they define the scope of the legislation.

An item by item analysis of my recommendations follows:

1. I have added the word 'routine' as a modifier of the types of examinations under Section 370 (1) (A). The use of this term would allow a degree of flexibility such that the Secretary, hopefully with the advice of a panel of experts, could develop reasonable criteria for which examinations, of the more than 800-1000, it is necessary to develop national standards and proficiency testing and which types of laboratories, of the hundreds of specialized types in existence, it is necessary to regulate. At least this degree of flexibility from our standpoint, while not optimum, is absolutely essential.

2. Elimination of the word 'biophysical'. This term is fraught with misinterpretation because it implies procedures to measure or record the emanation of various types of energy from the human body. I am convinced it is not the intent of the Congress to regulate the performance and interpretation of electrocardiographic, echocardiographic, electroencephalographic, sonographic, thermographic, electromyographic, cardiopulmonary, pulmonary, and even auscultatory procedures since these are highly specialized procedures which are not ordinarily considered to be clinical laboratory procedures. The term 'biophysical', however, could be interpreted to cover such procedures, and for this reason it is best to eliminate this ambiguous term.
3. Elimination of the words 'or other'. It is precisely the use of such vague terminology which allows the growth of mindless bureaucracy. Precision in definition is the one safeguard against future misguided regulatory zealotry. The Congress should define what it wants, and if future extension of regulatory authority is necessary, the Congress should then redefine but not leave that decision up to others.
4. Exceptions -
  - 370 (1) (A) (i) - This exception is the one to which I addressed a portion of my testimony. It would assure that those procedures performed by a licensed physician, dentist or podiatrist would be exempt. It should be kept entirely separate from proposed 370 (1) (A) (ii) because, pending the results of a study, it is conceivable that 370 (1) (A) (ii) could be altered while 370 (1) (A) (i) should remain as proposed.
  - 370 (1) (A) (ii) - This exception is in recognition of the request by D.H.E.W. that physician office laboratories be exempt, pending a study of the problem. We agree with this philosophy that the nature and extent of the problem should be precisely defined before its solution is created, and we urge this exception be adopted.
  - 370 (1) (A) (iii) - This is the present exemption 372 (3) (D) which we believe to be absolutely essential to maintain freedom of scientific inquiry. We feel it is most appropriately placed here.
  - 370 (1) (A) (iv) - This is a new provision which is added to provide a very necessary degree of flexibility. It takes cognizance of the fact that there are a number of specialized laboratories which perform complex or almost unique procedures on patients. Some of these laboratories receive specimens from all over the world. The volume of tests may be such that possibly it is not productive to perform the procedure except in one or several centers in the world. Under such circumstances there is no way proficiency testing or national standards could, or should, be devised or enforced. These laboratories should be exempt. It also recognizes that there are many tests performed which require subjective interpretation by a

Senator Javits

- 3 -

March 19, 1979

practitioner, and, hence, are not of a quantitative nature such that national standards can be devised. These also should be excluded.

I apologize for the length of this letter, but I felt it important to share with you my reasons for making the alterations I would propose. I have also taken the liberty of enclosing a copy of the Massachusetts Medical Society proceedings mentioned in my testimony in case you have not had an opportunity to see this document.

Yours sincerely,

Peyton E. Weary, M.D., Chairman  
Council on Governmental Liaison  
American Academy of Dermatology, Inc.

PEW/bp

Enclosures



## "PART H - CLINICAL LABORATORIES"

## "DEFINITIONS

"Sec. 370. As used in this part -

"(1) The terms 'laboratory' and 'clinical laboratory' mean

(A) a facility for the routine biological, microbiological, serological, chemical, immunohematological, radio-immunological, hematological, (b+eophysieat), cytological, or pathological (or-eether) examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of health of, humans, except -

(i) a facility, or portion of a facility, used by a licensed practitioner of medicine, dentistry, or podiatry to personally perform diagnostic procedures or examinations on materials from the practitioner's own patients or

(ii) a facility, or portion of a facility, which is located in the office of, and operated by, a licensed practitioner of medicine, dentistry, or podiatry, or a group of such practitioners, and in which the only tests or procedures performed are routine procedures performed in connection with the patients of such practitioner (or practitioners) or clinic, or

(iii) a facility in which the tests or procedures which are performed are primarily tests or procedures for biomedical or behavioral research, or

(iv) a facility, in which only very specialized or uncommon laboratory procedures or tests are performed, or tests which require interpretation by a licensed practitioner of medicine, dentistry or podiatry in order to express the results and thus are not subject to national standards, or

(B) a facility for the collection, processing and transmission of such materials for such purposes, other than a facility exclusively engaged in the collection or processing of human blood or its components intended for transfusion or further manufacturing.

\* NOTE - Where new words are added to existing language these are underlined. Where existing language is eliminated these words are bracketed and crossed through, i.e. (biophysieat)



Senator JAVITS. Thank you very much, Mr. Chairman. You have been very kind and indulgent.

Senator KENNEDY. Thank you.

Senator Schweiker?

Senator SCHWEIKER. Doctor, let me understand the answer you gave to Senator Javits. Is it your conception that we do or do not need a national standard for  $x$  number of tests? In other words, is it your conception that the Federal Government should set a national standard for a specific test procedure or not?

Ms. DAVIS. No, sir, that is not what we are suggesting. We are suggesting that the Federal Government should say that there do need to be quality controlled standards and technologies in place in laboratories.

The regulations will not spell out that it needs to be thus and such for hemoglobin or thus and such for something.

Senator SCHWEIKER. I would never gamble on what the regulations will spell out. That is half of our life here.

Ms. DAVIS. You can be sure we would object to that very much.

Senator SCHWEIKER. That is exactly why this is an issue, because regulations always spell out what we do not intend, and that is half the battle.

Ms. DAVIS. We do not want that.

Senator SCHWEIKER. I understand what you said, and that is in answer to my question. Dr. Weary, why then are you concerned on this issue? In other words, what part of the bill or language do you see that permits what you perceive here as some kind of loophole? Your presumption is that it would prescribe certain tests, standard tests, I gather.

Dr. WEARY. Senator Schweiker, first of all, I believe that I am approaching it from what I would guess is sort of the scientific approach, and that is that you have to define whether there is a problem and the magnitude of the problem and then design a treatment for it.

Let me take an example. There are probably 82 or more what I would call, specialty type laboratories in the University of Virginia Hospital that are not part of the regular clinical laboratory.

Now, each of these laboratories may do one or two very special procedures. If one is to develop proficiency testing for these laboratories for each of these procedures, then one has to develop national standards for each of the tests that are run, because it is not fair to test the proficiency of a technician doing a Lupis Test, called ANA, for some other procedure when that technician may only have done that procedure for the last 5 years. It is not appropriate to test that technician to run a glucose, if the person has not done it.

So that what you do is you open up Pandora's box. You have to then develop national standards of proficiency testing for all of these procedures. It is just almost inconceivable that this could be done in an effective way without a tremendous cost, and that is the problem.

The suburban hospital laboratories will all come under this. The medicare mill, and medicaid mills will all come under this bill. The main intrastate hospital laboratories of all sizes will come under this.

What we are talking about are specialized types of laboratories that do one or two very highly specialized procedures, and I do not see how they can be regulated nationally.

Senator SCHWEIKER. Dr. Davis, what is your response to that. Do you concur or not?

Ms. DAVIS. I guess I am having a little difficulty understanding what Dr. Weary is trying to say or perhaps the laboratories at the University of Virginia are set up differently.

Senator SCHWEIKER. I think he is saying, Dr. Davis, that in essence you cannot measure proficiency of a medicaid mill unless you set up some standards for the test they are performing. That is what I understand he is saying.

Is that not true, Dr. Weary? Is that not what you are saying?

Dr. WEARY. Yes; I am saying that very much, and I am saying there are ways to simplify this whole process of measuring proficiency without having to measure it for hundreds and hundreds of different tests.

Senator SCHWEIKER. So he is saying, in essence, that you cannot measure a medicaid mills performance without actually setting up a standard for the tests that they are normally performing. Now, that is the issue, Dr. Davis.

Ms. DAVIS. What he is saying though, is talking proficiency of laboratories on the one hand where we talk about proficiency test samples being sent in and they are analyzed to see if they can get the right answer and making sure that the people performing the test are competent. I understand that. That is two different things.

Senator SCHWEIKER. He concurred with that, Dr. Davis. He said that.

Ms. DAVIS. What he is saying—and there is a provision in this bill that the testing for competence of the individuals will be on a job related basis. He is saying if they are only doing one test, they should not be expected to take an examination on anything else.

And that is what I say. That is a little unusual. Most laboratories that I am familiar with do more than one test. In fact, you can organize it into chemistry tests and hematology tests and microbiology tests and so forth, so that what the bill calls for now is for examination of individuals based on their speciality.

He is talking about something very refined, which is very unusual and perhaps some accommodation could be made for that.

Senator SCHWEIKER. I think part of this concern probably stems from this section of the bill. Let me read it to you. This gives power to HEW.

Include such other requirements as the Secretary determines necessary to assure consistent performances by such laboratories of accurate and reliable tests and other procedures and services.

Now, I could certainly construe that to mean exactly what Dr. Weary said. That may not be the intent of Senator Javits, and I am not at all differing with his point. It may not be your intent.

But this is where we get into fights about the regulations. Regulations come out and nobody intended that, and here is an authority that I would think could set up national tests. How would you read that particular paragraph?

Ms. DAVIS. Well, I would not interpret it in that manner. However, if you feel it is open to that sort of interpretation, it seems to

me that the legislative history could show that you do not mean for it to be that stringent and that picky.

Senator SCHWEIKER. Well, I think that is the issue, and I think this is why the bill has had trouble in the House, because of the ambiguity.

Senator JAVITS. Just one question. What is proficiency testing? What do you do?

Ms. DAVIS. Proficiency testing is an evaluation of a laboratory's ability to turn out an accurate and reliable answer. A sample comes to the laboratory. They analyze it. They send an answer back to some group or some agency which then grades them on that answer.

Now, the difficulty with the present way that proficiency testing is done is that when the sample comes to the lab, everybody knows that it is a proficiency test sample. So generally, human nature being what it is, it is not handled in a routine manner, and that is why the statement is made that proficiency test performance may represent the absolute best that a laboratory can do.

Your bill then provides for the opportunity for onsite testing. An inspector would bring in a sample and watch it being analyzed. He would see whether or not they got the best person in the lab to do it or whether they did it five times before they wrote down the results, to see whether or not it was treated in a routine manner.

Senator JAVITS. So that the legislative intent will be clear: If I said the purpose of this bill is to deal with the professional way in which samples are tested rather than the way in which they should be tested, would I be correct?

Ms. DAVIS. I believe so.

Senator JAVITS. All right. That is my intention.

Senator KENNEDY. Thank you all very much.

The next speaker is William P. Densmore, vice president, Norton Co., Worcester, Mass., board member of the Central Massachusetts Health Systems Agency. He is accompanied by a distinguished panel of Jacqueline Hanson who is president-elect of the American Health Planning Association and Immediate past president of Mid-America Health Systems Agency in Kansas City, Mo., and Harry Cain, executive director of the American Health Planning Association.

We are delighted to have you here today. We look forward. We are confident that the Norton Co., is prospering today even in your absence as it has so well in the past.

**STATEMENT OF WILLIAM P. DENSMORE, VICE PRESIDENT, NORTON CO., WORCESTER, MASS., BOARD MEMBER OF CENTRAL MASSACHUSETTS HEALTH SYSTEMS AGENCY; ACCOMPANIED BY: JACQUELINE B. HANSON, PRESIDENT-ELECT, AMERICAN HEALTH PLANNING ASSOCIATION, AND IMMEDIATE PAST PRESIDENT OF MID-AMERICA HEALTH SYSTEMS AGENCY; AND HARRY P. CAIN, PH. D., EXECUTIVE DIRECTOR, AMERICAN HEALTH PLANNING ASSOCIATION**

Ms. HANSON. Thank you, Mr. Chairman, members of the subcommittee. My name is Jacqueline Hanson. I am president of the American Health Planning Association, which is the national association, as you know, of State and local planning agencies, their

boards, their staffs and their many individual and corporate affiliate members.

I am also, for your information, a consumer member and immediate past president of the Mid-American Health Systems Agency in Kansas City. With me, as you have already acknowledged are William P. Densmore who is vice president of Norton Co., Worcester, Mass., and is an active consumer board member of the HSA in that area. On my left, Harry P. Cain who is executive director of the American Health Planning Association.

We have asked Mr. Densmore, this morning, to make a few comments from his prospective as a volunteer and active member of an HSA which is currently engaged in the planning process at the community level.

Following his brief comments, I will summarize the balance of our testimony in the interest of your time, Mr. Chairman and members of the committee, and I will now turn the testimony to Mr. Densmore for a few minutes.

MR. DENSMORE. Just to briefly explain my presence, the Norton Co., is a multinational company with sales of about \$1 billion, employing 23,000 people worldwide, and I am general manager of its U.S. Grinding Wheel Division which accounts for about two-thirds of our 4,000 employees in the Worcester complex. So it is a major factor in the central Massachusetts economy.

I have been invited here today because I represent major purchasers of health services on the central Massachusetts HSA board of directors. I am involved and concerned because we share in the national health care crisis in central Massachusetts due to runaway costs, lack of access for certain population groups and an inadequate health promotion or prevention effort.

It is a critical issue to business. For our Worcester complex, we have seen our health care costs go from \$1 million to \$4 million per year in the last 10 years. So it has become a very significant cost factor.

I have been on the local health systems agency board for nearly 2 years, and I am very impressed with what is being done. I am impressed with the concept of local integrated comprehensive planning. I am impressed with the participatory process that has been set up.

I am impressed with the competence and the dedication of the staff and the many volunteer board members and committee members. I am impressed with the balance that the HSA approach represents between Government regulation and private initiative.

I am impressed with the 800-page comprehensive 5-year plan that has been developed for central Massachusetts, covering all components of health care. This seems crucial in a system which is characterized by fiercely independent institutions and professional groups who have resisted efforts to cooperate and share services without some form of Government intervention.

And I am impressed with the thoroughness and the objectivity of the determination of need reviews conducted by the staff and project review committee and the board, and I am impressed with the results to date in implementing the plan.

Yet the concept of comprehensive health planning and the concept of determination of needs studies and certain aspects of the

plan are very controversial. There is a big problem of explaining the program and building acceptance.

Hospital trustees, hospital administrators and doctors tend to be suspicious if not hostile. The excess bed issue is threatening to many people, and the section of the plan which deals with family planning is necessarily controversial.

So there is a lot of objection. But we have found that the explaining and the persuading and the constituency building which is necessary to put action into planning can be done, and I will submit the rest of my testimony which gives a brief summary of the approaches that we have used.

I am convinced that the HSA integrated planning and CON process is needed and must be part of your national health care policy, and I was delighted to hear from your opening remarks that you apparently feel it is great, too.

Thank you.

Senator KENNEDY. Thank you very much.

Ms. HANSON. Thank you, Mr. Densmore.

Today we do appear, as I am sure you realize, in support of S. 544. We feel that planning is very definitely making an impact on the health care in communities across the country.

A full report of the performance of health planning agencies in the past 2 years is submitted as part of our testimony for your study and analysis. This study does provide for you usable data on the experience of health planning agencies covering 88 percent of the U.S. population.

Without dealing with the specifics contained in that study which I know you will have an opportunity to deal with, we do have figures relative to capital applications, positive and negative comments which lead us to say, conservatively, that in the last 2 years planning agencies have prevented \$8 of unnecessary capital investment for every dollar which has been spent on health planning.

We feel this is a significant figure and one that can be readily supported by the study which we have submitted to you.

We assume that Congress recognizes that some of the mandated responsibilities of health planning agencies are not yet being met. The lack of HEW regulations on review and approval of proposed uses of Federal funds and on appropriateness reviews, as were specified in Public Law 93-641 back in 1974, have hampered the agency's performance in these areas.

We eagerly await that kind of performance by HEW that Congress and the Department expected of the health planning agencies. We particularly appreciate the bill's increased support for the minimally funded agency, its appropriate strengthening of the roles of State Governors, its concern for, although not your specific approach to, fostering better integration of mental planning with health planning, and its proposed 3-year designation of agency and its requirement that CON decisions be consistent with the State health plan.

However, there are a few concerns that we hope will be recognized during the committee markup. Where it is appropriate we will submit mandatory language for your consideration.

Considering the impact of all the proposed procedural changes in S. 544, each of which may be highly reasonable by itself, the



combination of procedural changes may disrupt the agency's performance seriously enough that we earnestly request that as the bill is marked up that there be consideration that agencies be permitted time to implement changes gradually.

When it is clearly the intent of the law that the health systems agencies perform activities which facilitate voluntary closure or conversion or a combination of existing facilities, we think it is urgent that members of HSA's and SHCC's are protected from unnecessary suit, including antitrust suits.

We support the bill's intention to promote HMO's by requiring that they be evaluated within a specifically developed HMO frame of reference, and we further support a requirement that would prevent HMO's from being discriminated against in State certificate-of-need programs.

We are concerned, however, over the bill's prohibition of any coverage of HMO ambulatory services. If you apply the principle of equity, it could be that other resource intensive ambulatory facilities and services could be removed from the purview of the planning agencies which we would find regrettable.

We would support a 2-year or a 3-year, as the administration proposed, cycle for the review and revision of HSP's except where there are underdeveloped sections which could be determined by the SHCC.

The HSA must be permitted to have time to do work of substance not just of form. We particularly are interested in the retention of very tight criteria for the resignation of HSA areas.

Any arbitrary or capricious change of an areas boundaries can disrupt every process and product of the affected HSA, and we could not, in good conscience, take a minute to mention our serious concerns regarding some of the proposed administration amendments to Public Law 93-641, several of which we feel carry some grave implications for the planning process.

We were interested in and are supportive of many of the recommendations that were made earlier in this presentation by the administration. Until a couple of days ago, we understood there would be a proposal in the administration bill that would include amendment to section 1536, allowing governors to eliminate HSA's in any States having only one agency and placing their function with the SHPDA. There currently are, as you know, 13 such States.

There could be many more if area designation criteria had been softened as the administration bill we feared would be proposed. It would eliminate the now required public-private partnership and would transform the affected areas into exclusively State governmental planning units in which citizen volunteers only could serve at the sufferance of the State.

We agree that there are some probably serious structural problems in single HSA states, and appended to our testimony you will find a proposal for dealing with them within the basic concepts of the law.

Three issues that concern us relative to the administration proposals. The administration proposes to permit the Governor to modify the State health plan and the State SHP at will, requiring that only the Governor consult with the State health coordinating council and publicly state his reasons for change.

This seems to us to invalidate the entire health planning process. If such potential for eradication of all the time and effort expended by hundreds or thousands of community volunteers exists, the entire process cannot help but suffer.

Given the proposed requirement that certificate-of-need decision be consistent with the State health plan, which we do support, such extraordinarily wide latitude for the Governor would create far too many incentives for ad hoc amendments, we feel, to the State health plan.

Senator KENNEDY. Do you think on that point—that is one of the recommendations of the administration that it would undermine the effectiveness of the kind of work that is being done at the local level?

Ms. HANSON. Senator, I do. I think the process that finally arrives at the HSP's is one that involves such concentrated input, a series of public hearings, community input. Then when it finally arrives at the point at which everyone is comfortable with it, for all your volunteers as well as your professional staff to think that suddenly all of that could be changed or disseminated, I think, would be morally undermining and I also think it kind of removes the sort of accountability that I thought this bill had been encouraging.

I really think it would.

Senator KENNEDY. You would agree with that, Mr. Densmore?

Mr. DENSMORE. Yes.

Ms. HANSON. Next we have been advised, and I keep saying "advised" because at the time we wrote our testimony—in fact, we have yet to see the administration bill—we have been told the administration bill, and have heard, will give the Secretary total authority to specify which institutional health services must be reviewed for their appropriateness on an institution-by-institution basis.

This, again, seems something that should be left to the local communities to decide in view of what we feel is the intent of the original law, Pub. L. 93-641. Wide variations in institutional health services that exist throughout the country, we suggest, would make it extraordinarily difficult to apply one standard for all.

Finally, it is our understanding that there also in this administration bill will be a provision calling for total Secretarial discretion in determining the amount of grant funds to be allocated to the HSA.

Per capita funding formula, as was stated earlier, would be eliminated. We think that is a highly questionable provision. But the consequences on the ability of the planning agency to apply any reasonable degree of sound program or fiscal management procedures for their planning, we think, would be very difficult.

The other issue that I think is a rationale concern of the agency and the AHPA representing them is the implication that HSA's are nothing but part of the system at which the Secretary's discretion would decide whether agency A or agency B should get a certain kind of funding.

We realize, perhaps, there is nothing punitive or negative intended in the administration proposal. We think, however, totally elimi-

nating the per capita funding for this kind of a discretionary funding we think would be very dangerous.

The great strength of the agencies is that they are community based, they are broadly represented. They are agents of change, and we are charged with solving important problems in ways we hope are responsive to our local community situations.

Hopefully, the things we have pointed out as concerns to the administration will also be concerns to your committee.

At a time in our history when citizens are concerned about Federal spending and also concerned about Federal initiatives brought into their communities without very careful consideration of what local needs are, we feel that we are in a position to say that this is a Federal intervention that is appropriate.

We think the answer to why there should be continued Federal support and funding and endorsement of health planning are threefold.

The health planning law is interestingly the only major health legislation passed by the Congress which has been documented to reduce health care costs significantly. Again, I refer you to our study.

Second, the health planning law provides for full local involvement of all parties, consumers, provider, rich, poor, urban, rural, and they are all able to participate in the decisionmaking process.

And finally, the planning agencies are really captive of no special interest group. They represent as closely as it is ever possible to be represented a shared community prospective as to what constitutes good health care, what the unmet needs are in a health service area, and this has been applied across the country, we feel, with a track record, so far, of success.

Volunteers and staffs of the health systems agencies, and the SHCC's and the SHPDA's worked hard the last 3 years for their communities, for their regions and for their State. They have done it with, we feel, some degree of success. Of course, there is still some more success ahead.

We think that your support and confidence to expand the program that already exists, we think, will result in some remarkable achievements in the future. Thank you.

Senator KENNEDY. Thank you very much. That summary is really what was intended with the program, not without some complications and some difficulties. We are strong believers that we have the framework set, that we should adjust and tune it a bit without shaking it up, give it an opportunity to function and work.

And the purpose was just as you identified, to save the kinds of resources, to bring local responsibility in terms of making decisions affecting health care within the community, believing the people within those communities are going to be concerned and active and involved in insisting that they involve themselves in decisions affecting their lives, the lives of their children and parents, and doing it in a way in which, in a framework in which we have the providers and the consumers and those that are impacted by these decisions are working in a synergistic way to really make some sense out of health policy. I am a strong believer that that is the way we ought to be moving.



It is encouraging with your statistics in terms of the savings of resources. I have one question. Mr. Densmore, how do you develop the kinds of support within your locality when you are making some awful tough and difficult decisions where you are saying yes to one group; no, to another; and where you are under a general framework of limitations in terms of where the big Washington is in the back, somewhere in the background.

How can you really make these decisions in a way that will build the kind of support, particularly when you are—as this process moves on for a longer and longer period of time, you are going to have to make tougher and tougher kinds of decisions. What can you tell us about it? I would just be interested in what your own sense is.

Mr. DENSMORE. I think we are only part way down the road, but my observation is, as I said in the testimony, that there is a very well thought out participatory process involved in developing the plan in the first place.

But still it is a small percentage of the 675,000 people in the area, and when the rest of them read about it in the newspaper, it can become very controversial and political.

So we have undertaken a major effort to put our story across through putting together a reasonable professional slide-tape story on the health systems agency, and we have had this available for a month or so.

We have presented it to the senators and representatives of central Massachusetts, to the Worcester City Council, to a number of hospital trustees and so on, and we find that when we do a good job of putting the whole story across as to the health care crisis and the role of health systems agencies in the planning process and the major components of each of the 14 elements of the plan and focus on some of the priority issues at the end, that we get a good reception, and we think we are beginning to build good understanding and support.

Senator KENNEDY. Just as a point of information, Norton Co., what is sort of your front end planning? Are you thinking 2 years ahead, 3 years ahead, 10 years ahead?

Mr. DENSMORE. Ten years. And more formally for 5 years.

Senator KENNEDY. It seems to me that this is what we have to try and do. It seems to me that that expands alternatives rather than shrinks them. It seems to me that when we do not give thought to what the various factors are going to be down the road, we limit our alternatives often in instances to the least desirable.

Ms. HANSON. Could I just make one comment on the question you asked Mr. Densmore, because he said he thinks we are only part way down the process?

I think the health systems agencies, like, I guess, the antedote, originally started preaching and then meddling, and then as more difficult decisions have come along, I think we really have gotten people's attention, maybe originally not in a positive way, but I think ultimately in a positive way, and I sense in my own community more and more awareness that they know that these citizen volunteers are making difficult decisions, not arbitrary ones, not philosophical ones, not those that you simply filter through what-

ever your religious affiliation is, but they are difficult decisions for the future.

And I think as more public awareness comes of that there is less hostility, a little more respect and most importantly more people saying, "Gee, I might want to do that, too."

And I think that is the most exciting part—people's willingness to participate—not just when it impacts on them personally but because they can perceive there is a community benefit there.

Senator KENNEDY. And a key element to that, as I gather from what you said earlier, is that their decisions which are made at the local level are going to be the ones that are going to be respected as the process functions and works. That is absolutely essential. You would agree with that?

Mr. DENSMORE. To me that is a major sales point in this story that we are trying to get across that it is a local agency, making local decisions, and we hope to persuade people that that is a preferable alternative.

Senator KENNEDY. I have no further questions. But I want to recognize Jake Gibson who is the head of our master planning program at this hearing. Mr. Gibson for a number of years had the opportunity to talk to me about this program in the State.

Ms. HANSON. And a valuable member of the AHPA board.

Mr. DENSMORE. I might also say that we have with us in the audience President Mary Alexander and the Executive Director Bob Higgins, and Assistant Executive Director Bob Bradfree.

Senator KENNEDY. Just as a final point before yielding to Senator Schweiker, I would indicate that any program that will have national health insurance is going to build on this concept. That is the only way I think we can do it is having these kinds of involvement in decisionmaking in communities.

Senator SCHWEIKER. I would just like to ask Ms. Hanson. You heard some of this discussion earlier this morning about the administration's recommendations to change the bill before us and relax the 1-year planning requirement. My question to you is how much effort is putting a master plan together for the year in terms of your resources and efforts? And No. 2, do you concur with the idea that there should be some figure other than an annual plan?

Ms. HANSON. Senator, I think one of our recommendations is at least there be a 2-year planning cycle, and we were not aware the administration was going to suggest three.

Senator SCHWEIKER. Neither was I.

Ms. HANSON. We could live with that nicely. Annual update, if you got parts of your plan that are basically underdeveloped or that you have purposely deferred because you know you will be coming back to it next year, I always think that anytime that's been done, you should always continue developing those components of the plan until they are correct.

In terms of the whole plan, the idea of updating it annually actually, as I mentioned in my summary, you end up dealing with form and not much time to deal with substance. I think it is so important that the agencies get an opportunity to look at where they have come since they made these recommendations and set these goals in their plan.

Even though you have got an annual implementation plan which directs your activities, for you to have to update your health systems plan annually just seems like an enormous time commitment that could, perhaps, be better spent in community education, in conducting informational things that could be useful to your community and to your constituents.

We are very much in favor of at least the 2 and I say 3 would be all right, too, but at least 2 years would be great.

Senator SCHWEIKER. Dr. Cain, do you have a statement or a summary?

Dr. CAIN. I do not think so.

Senator SCHWEIKER. We thank you all very much and we certainly will take quite seriously your proposals. I think it is very excellent to have a group come in with very specific proposals, well summarized, very helpful to us.

Thank you.

[The prepared statement of American Health Planning Association follows:]

AMERICAN HEALTH PLANNING ASSOCIATION

Anthony T. Mott  
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Jacqueline B. Hanson  
*President-Elect*  
Bernardo Benes, Ph.D.  
*Immediate Past Pres*

James R. Kamney, M.D.  
*Secretary*  
Otho Whiteneck, D.D.S.  
*Treasurer*  
Harry P. Cain II, Ph.D.  
*Executive Director*

TESTIMONY OF

JACQUELINE B. HANSON  
PRESIDENT-ELECT

WILLIAM P. DENSMORE  
CONSUMER BOARD MEMBER  
CENTRAL MASSACHUSETTS HEALTH SYSTEMS AGENCY

AND

HARRY P. CAIN II, Ph.D.  
EXECUTIVE DIRECTOR

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

SENATE LABOR AND HUMAN RESOURCES COMMITTEE

MARCH 16, 1979

March 16, 1979

Mr. Chairman, Members of the Subcommittee:

My name is Jacqueline B. Hanson. I am President-Elect of the American Health Planning Association, the national association for state and local health planning agencies, their boards, their staffs, and our many individual and corporate affiliate members. I am also the immediate past president of the Mid-America HSA in Kansas City. With me are William P. Densmore, Vice President of the Norton Company of Worcester, Massachusetts, and an active consumer board member of the HSA in that area, and Harry P. Cain, Executive Director of the AHPA.

We are here today representing more than 50,000 people who volunteer their time and efforts as members of boards of directors, subarea councils, advisory groups, and other bodies of health planning agencies. Their concern is for improving the health and health care systems serving all Americans.

Health planning is working. We need your support and the support of Congress in passing three-year renewal legislation which will give long-range stability to our efforts to promote effective, credible health planning at the community and state levels.

We have asked Mr. Densmore to present this testimony today to provide the Committee with the perspective of an active volunteer consumer who is currently engaged in the planning process on the community level.

(Mr. Densmore:)

A year and a half ago when you first introduced the health planning renewal bill as S. 2410, it was too early in the development of many state and local planning agencies for us to report with certainty on the impact of these agencies

March 16, 1979  
AHPA S. 544 Testimony  
Page 2

their communities. Today, as we appear in support of S. 544 in the 96th Congress, we can confidently report that planning is making an impact on health are in communities all across the country. The impact is being felt in two major areas: cost reduction and health care systems improvement.

Nearly all of the local planning agencies are fully designated and have completed their initial health systems plans. A large number have had the opportunity to revise these plans on the basis of experience. They have defined the health care needs of their areas and addressed the means for pursuing goals and objectives in each area where better or more accessible health care is required. They have worked actively through the existing review programs to curtail unneeded new health care capital and operating expenditures.

A full report on the performance of health planning agencies in the past two years is submitted with this testimony for your study. The study provides usable data on the experience of health planning agencies covering 88% of the United States' population.

Several findings should be emphasized. During the past two years, the total investment in health planning in the areas covered was approximately \$330 million, or \$1.69 per capita (nearly 90% in Federal dollars). In that same time, the amount of proposed capital investment reviewed by these agencies was \$12 billion dollars, or \$ 78.50 per capita. The amount disapproved or discouraged was \$3.4 billion, or \$26.45 per capita. If we consider only those capital investment proposals that were officially denied, a total of 2.3 billion dollars or \$13.79 of unnecessary capital investment per capita has not gone forward. We can say, therefore, using conservative estimates, that in the last two years planning agencies prevented eight dollars of unnecessary capital

March 16, 1979  
AHPA S. 544 Testimony  
Page 3

investment for every dollar spent on health planning. And the accompanying operating costs saved as a consequence of these capital investment denials, again by conservative estimate, would exceed 10 billion dollars for the decade of the 1980s.

Capital investment review typically utilizes much less than half of a planning agency's time and resources. The majority of their efforts are directed toward other plan development, implementation, and technical assistance activities. These activities have a two-fold benefit. First, they enrich and enhance community health resources. Secondly, they have significant long range cost control implications. We wish to stress that all cost containment is not bound up in capital and facilities control.

Consider, for example, the important cost-benefits to the population of: development of new ambulatory care facilities; assistance in the design of health promotion programs in municipal hospitals; cooperative meetings with an area's radiologists to establish plans for future placement of CT scanners; providing assistance in the development of feasibility studies for the establishment of HMOs; leadership consultation and collection of data which promotes the merger of hospitals in a large city; having underserved areas designated as "underserved" for purposes of Federal funding eligibility; providing technical assistance and organizing the community in support of rural health initiative planning grants; assisting in the recruitment of physicians for underserved counties; and arranging public service radio announcements on child immunizations. Each of these activities results in concrete improvements in the way health care is delivered and received. They are documented in the study.

March 16, 1979  
AHPA S. 544 Testimony  
Page 4

We would like to emphasize the contribution of the more than 50,000 volunteers who participate in the planning process. These volunteers have, by conservative estimates derived from a study of participation in the southeast, contributed over 4 million hours, exclusive of travel or preparation time, in support of planning for better health care in their local communities over the past two years. This represents over \$50 million dollars of in-kind "volunteer" contributions provided by highly skilled and thoroughly committed professionals and lay persons in pursuit of community-based health care objectives. These volunteers need and deserve an affirmative response and a vote of confidence from Congress concerning their involvement and efforts on behalf of their communities.

We presume that the Congress recognizes that some of the mandated responsibilities of the planning agencies are not yet being met. The lack of HEW regulations on review and approval of proposed uses of federal funds and on appropriateness reviews, as specified in P.L. 93-641 in 1974, have hampered agency performance in these areas. We eagerly await the kind of performance by HEW that you and the Department expect of the health planning agencies.

The analysis of the legislation which we will submit for the record will indicate that in most particulars we support S. 544. We believe it provides additional impetus for continuation of a health planning process that has been successfully initiated.

We particularly appreciate the bill's increased support for the minimally funded agencies, its appropriate strengthening of the role of the State Governors, its concern for (although not the specific approach to) fostering better integration of mental health planning with health planning, its proposed three-year



March 16, 1979  
AHPA S. 544 Testimony  
Page 5

designations of the agencies, and its requirement that CON decisions be consistent with the State Health Plan.

In addition, we ask that the following concerns be recognized in Committee mark-up. (Where appropriate we will submit amendatory language for your consideration):

1. Let us weigh the total impact of all the proposed procedural changes, each of which may be reasonable by itself, but the combination of them all may seriously disrupt the agencies' performance. At the least, allow a long enough time to implement the changes gradually.
2. Protect the members of the HSA and SHOC from unnecessary suit, including anti-trust suit, when it is clearly the intent of the law that the health systems agency shall perform activities which facilitate voluntary closure or conversion or combination of existing facilities.
3. We support the bill's intention to promote HMOs by requiring that they be evaluated within a specially developed HMO frame of reference. We further support a requirement that would prevent HMOs from being discriminated against in State CON programs. We are concerned, however, over the bill's further proscription of any coverage of HMO ambulatory services. We fear that the principle of equity might push for the removal of other resource intensive ambulatory facilities and services from the purview of the planning agencies.
4. We would support a two-year cycle for the review and revision of the HSP and the SHP, requiring annual revision/improvement only for incomplete or underdeveloped sections of the HSP or SHP as determined by the SHOC.

March 16, 1979  
AHPA S. 544 Testimony  
Page 6

5. We hope you will retain very tight criteria for the redesignation of HSA areas. Any arbitrary or capricious change of an area's boundaries can wreak havoc with every process and product of the affected HSAs.

We could not in good conscience fail to mention our serious concern regarding the proposed Administration amendments to P.L. 93-641, several of which carry grave implications for the planning process. I would like to discuss four of these in particular.

1. We understand that the Administration bill will include an amendment to Section 1536 allowing Governors to eliminate HSAs in any states having only one HSA and placing their functions with the SHPDA. There currently are 13 such states. There could be many more if area redesignation criteria are softened as the Administration's bill proposes. We consider this idea to be completely at odds with the basic intent of P.L. 93-641. It would eliminate the now required public-private partnership, and would transform the affected areas into exclusive state governmental planning units in which citizen volunteers could serve only at the sufferance of the state. Any solid sense of checks and balances could be eliminated at will. We do agree that there are some structural problems in single HSA states and we have developed a proposal for dealing with them within the basic concepts of this law.
2. The Administration also proposes to permit the Governor to modify the State Health Plan and the Health Systems Plans at will, requiring only that he consult with the State Health Coordinating Council (SHCC)

March 16, 1979  
AHPA S. 544 Testimony  
Page 7

and publicly state his reasons for his changes. This would seem to us to invalidate the entire process. If such potential for eradication of all of the time and effort expended by hundreds or thousands of community volunteers exists, the entire process will suffer. Particularly given the proposed requirement that Certificate of Need decisions be consistent with the State Health Plan (which we support), such extraordinarily wide latitude for the Governor would create too many incentives for ad hoc amendments to the State Health Plan.

3. We also have been advised that the Administration bill will give the Secretary total authority to specify which institutional health services must be reviewed for their appropriateness on an institution-by-institution basis. This again seems to us better left to states and local communities to decide in view of the intent of P.L. 93-641 and the wide variations in institutional health services which exist throughout the country.
4. Finally, it is our understanding that the Administration bill will again contain a provision calling for total Secretarial discretion in determining the amount of grant funds to be allocated to each HSA. The per capita funding formula would be eliminated. Not only is the intent of such a provision questionable, but its consequences on the ability of planning agencies to apply any reasonable degree of sound program or fiscal management procedures would be severe. Moreover, the implication that the HSAs are considered by the Department to be puppets on the end of the Secretary's string, to be jerked around as he chooses, is simply outrageous. The great strength of these agencies is that they are community-based, broadly representative agents of change, charged with solving important problems in ways responsive to their own situations.

March 16, 1979  
AHFA S. 544 Testimony  
Page 8

In closing, we ask rhetorically: Why should the Congress support planning agencies at a time when people are concerned about Federal spending and do not want Federal initiative brought into their communities without careful consideration of local needs: The answer is three-fold:

1. The health planning law is the only major health legislation passed by the Congress in recent years which has been documented to reduce health care costs significantly.
2. The health planning law provides for full local involvement of all parties, consumer and provider, the rich and the poor, urban and rural, in the decision-making process; and
3. Planning agencies are captive of no special interest group. They represent, as closely as it is possible to be represented, a shared community perspective as to what constitutes good health care and unmet needs in health service areas throughout the country.

The volunteers and staffs of these agencies have worked hard during the past three years for their communities, for their region, for their state, and for their nation. They deserve your support and your confidence, so they may expand upon the remarkable progress already achieved. Thank you.

## AMERICAN HEALTH PLANNING ASSOCIATION

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President-Elect  
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Immediate Past Pres.

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Treasurer  
Harry P. Cain II, Ph.D.  
Executive Director

January 30, 1979

## RESOLVING THE SINGLE HSA STATE PROBLEM\*

As approved by the AHPA Executive Committee - January 29, 1979

There has been considerable attention focused on the problems with the structure of single health systems agency states. Proposals have been offered by the National Governors Association and the Administration on the basis of input received from their constituents as well as from a General Accounting Office study of health systems agencies and the Arthur D. Little studies. The recommendations from those studies were summarized in a paper by Luci Swanson, Chairman of the Government Policy Committee, and sent to all single state HSA and SHPDA executives. In addition, there are currently under development proposals from the single state health systems agencies themselves which will be discussed at least in preliminary form at this meeting.

It is the belief of the AHPA staff that the Administration and the National Governors Association will make strong recommendations for drastic change in the structural situation of single HSA states. AHPA must have a reasonable and easily defensible approach to this problem. We have considered carefully the options currently under discussion in respect to relationships among the governor, the SHCC, the SHPDA, and the HSA in the single HSA state. The resulting five point proposal is set forth for discussion by the committee. Three of these points follow the basic agreements reached in Senate - House

\*AHPA Government Policy Committee issue paper supplement to the paper issued by Luci Swanson 1/15/79 concerning potential amendments to P.L. 93-641.

9th Annual Meeting — Sheraton-Boston Hotel — Boston, MA — May 31-June 3, 1979  
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conference discussions of the 95th Congress, and follow directly from the policy orientation taken by the Senate and House bills toward the single HSA state issue. One of the two additional points addresses the perceived imbalance between HSA and state interests at the level of the SHCC. The second point attempts to facilitate what many single HSA states have been doing for some time -- that is, to work out among themselves a system for efficiently translating the requirements of P.L. 93-641 into shared responsibilities with a minimum of unnecessary duplication or confusion in roles in such areas as plan development and review.

The five point proposal for single HSA states is as follows:

1. There shall be no additional area redesignation requirements beyond those presently required under the law except to achieve more efficient and effective health planning areas.
2. The 1536 option shall not be expanded to cover additional single HSA states.
3. The governor may appoint the SHCC chairperson.
4. The governor may appoint up to 50% of the SHCC from other than HSA representatives. (No HSA should be entitled to a majority position on the SHCC).
5. The SHCC, in consultation with the governor, may approve a functional division of labor between the single state HSA and the SHPDA, but only if this new division of labor involves

AHPA/Single HSA State  
January 30, 1979  
Page 3

functions, goals, and priorities already prescribed by P.L. 93-641. In addition, if this new division of labor involves a change in a functional role for the SHCC (different from that specified in P.L. 93-641), the Secretary of HEW must review and approve any change in the SHCC role.

This proposal is designed to avoid disruption of existing working relationships in single HSA states (points 1 and 2); gives the governor an opportunity for input within the present framework of the law (points 3 and 4); fosters integrated planning between the SHPDA and HSAs, taking into account statewide policy (point 5); and most importantly allows the HSA and SHPDA, with approval of the SHCC, to work out procedures which best fit the needs of each single HSA state as a function of its distribution of services while providing for effective representation of local and substate interests (point 5).

AHPA:jlw

Second Report  
on  
1978 Survey of Health Planning Agencies

February, 1979

American Health Planning Association  
1601 Connecticut Avenue, N.W.  
Washington, D.C.  
202-232-6390

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## Table of Contents

Executive Summary .....	1-4
I. <u>Introduction</u> .....	5
Purpose.....	5
Scope.....	6
II. <u>Research Methods</u> .....	6
A. Form A and A-1 (CON/1122 reviews).....	6
B. Form B (Reviews of Proposed Uses of Federal Funds).....	7
C. Form C (Technical Assistance).....	7
D. Form D (Other Accomplishments, Frustrations).....	7
E. Editing, Validating, Abstracting.....	8
F. Some Methodological Problems.....	8
III. <u>Results</u> .....	12
A. Agencies/Areas That Responded.....	12
B. CON/1122 Reviews.....	14
1. Performance Period Covered.....	16
2. Los Angeles .....	19
3. "Unofficial v. Official".....	19
4. "Beds v. Equipment v. Renovation," etc.....	20
C. Proposed Use of Federal Funds.....	20
D. Technical Assistance.....	23
E. Other Accomplishments/Achievements/Disappointments.....	29
IV. Next Level of Analysis.....	33
V. Keeping the Results in Perspective.....	33
VI. Appendix A.....	36
VII. Appendix B.....	46
VIII. Appendix C.....	51

EXECUTIVE SUMMARY

This report summarizes the data obtained by the AHPA survey of health planning agencies concerning their activities for the 24-month period ending August, 1978. The data focus on five areas: (1) the formal review of capital investments proposed under State Certificate of Need Programs or "1122 agreements", (2) the "unofficial" actions by HSAs/SHPDAs that discourage capital investment proposals, (3) the review of proposed uses of Federal funds (PUFF), (4) the provision of technical assistance, and (5) major implementation problems.

The survey was conducted because some relevant major national policy issues concerning P.L. 93-641 -- cost containment, health promotion, etc. -- are being debated in the absence of any reliable data, from the nation as a whole, on the impact of the planning agencies. The Federal government has invested many millions of dollars in the development of the health planning agencies; States and localities have added more dollars to the investment; and thousands of individuals, citizen volunteers, have contributed millions of hours of effort. The two major objectives of the planning agencies are "cost containment" and "health care system improvement". The extent to which these objectives are being reached remains unknown, except on an anecdotal basis; hence, this survey.

*Who responded to the survey?....*

Eighty-one percent of the HSAs (166 of 204) and fifty-three percent of the SHPDAs (27 of 51) responded, giving us usable data covering 88% of the U.S. population. The respondents were well distributed across the United States, by region and by rural/urban character.

*What was the CON/1122 experience?.....*

**Major Findings:**

1. The reporting agencies reviewed \$12 billion in capital investment proposals (of which \$10.6 billion were in official Certificate of Need or 1122 applications).
2. \$3.4 billion of the proposed investments were disapproved (\$2.3 billion in official disapprovals).
3. In the hospital sector, 16,000 new beds were proposed (11,500 in official applications), of which 7900 will not be built (3700 officially disapproved).
4. For skilled nursing homes and intermediate care facilities, 114,000 new beds were proposed (85,000 officially). 49,000 did not get approved (20,000 officially denied).
5. The "operating costs" saved as a consequence of the capital investment denials are more difficult to quantify -- but would have to exceed \$10 billion for the decade of the 1980s.
6. For the reporting areas, the amount of proposed capital investment reviewed per capita, for those 2 years, was \$78.50 (\$65.15 officially); the amount denied was \$26.45 (\$13.97 officially).
7. The total amount invested in health planning per capita, for those two years, was \$1.69; and the review of proposed capital investments constitutes less than half of the planning agencies' major activities.

By charting the responding agencies according to their size (population served) and when they began doing OIG/1122 reviews, we discover that our findings on official reviews relate to 75% of the U.S. population, for the two years under study. Data relating to capital investment proposals discarded through "unofficial" but documentable HSA actions pertain to about 45% of the U.S. population.

While there are always methodological problems with this kind of survey, we believe that they have been recognized in this effort, and the appropriate caveats have been made (see Sections II. F. and III. A. in the full report). One of the most perplexing questions is, how does the planning/regulatory environment affect the performance of a planning agency. The following quote from one survey response was echoed by many of the agencies, and exemplifies the problem:

It should be emphasized that our HSA does much more than simply approve or disapprove capital expenditure proposals. We first seek to help the proponent of a project plan properly for a needed service. We help the applicant (provider) develop a proposal that is consistent with identified community needs. Most of the nursing home and home health care proposals developed in this area during the past four years are a result of this effort. As part of this "positive" planning process, as some like to call it, the HSA has discouraged or redirected substantially more applications (particularly for nursing homes, CT scanners and surgical centers) than it has disapproved. In most cases it is not possible to demonstrate this quantitatively. I believe it is fair to say, however, that this is where the HSA has been most successful. I am personally aware of projects and proposals for more than a dozen nursing homes, three CT scanners, three ESRD facilities, two proprietary hospitals, two proprietary free-standing surgical centers, and two proprietary "alcohol treatment centers" that have not been pursued or developed because of HSA (and in some cases also SHFDA) policies, plans and analyses.

#### *Puff Reviews.....*

Given the stage of agency development during the last two years, and the lack of HEW regulations on the subject, most agencies had not begun to "review and approve or disapprove" proposed uses of Federal funds, the so-called PUFF reviews. However, many agencies were reviewing proposed Federal grant/contract applications, in order to comment on them to the Federal funding agency. The full report provides enough examples of such reviews to provide a flavor of this activity.

#### *Technical Assistance.....*

Technical assistance provided by the planning agencies, as a major plan-implementation activity, consumes a large share of their resources. The kinds of technical assistance they provide clearly exemplify the nature of a planning agency's work. Some typical "technical assistance logs" are reproduced in the full report, from which we excerpt these examples:

*In a midwest HSA.....*

Provided technical assistance to municipal hospital to establish an ambulatory care center in conjunction with a health promotion program. Results to date include: 1) agreements made by two physicians to staff a primary care center which will be operated by a health service network; 2) tentative commitment from Blue Cross to provide grant support for the development of a demonstration health promotion program; and 3) commitment from Board of Trustees of hospital to reduce the facility's inpatient bed capacity. (130 Days of HSA staff effort)

Organized and conducted meetings with area radiologists to establish plan for future placement of CT scanners. (30 Days)

*In a northeast HSA.....*

Provided assistance in development of feasibility studies for establishment of HMOs in two Counties - one not funded, other still in planning stages. (5 days, Sr. Staff; 10 days, Jr. Staff)

Leadership, consultation and data regarding merger of two hospitals in a large city -- new corporation formed. (20 days, Sr. Staff; 10 days, Jr. Staff)

*In a western HSA.....*

Assisted Health Services, Inc., in submitting a designation request to DHEW to have most of the high desert portions of area designated as dental underserved area. Request granted August, 1977. (25 Days)

*In a southern HSA.....*

Organized community and provided technical support for Rural Health Initiative Planning Grants - three funded, one pending. (22 Days)

Assisted in recruitment of physicians for two medically underserved counties -- two physicians now practicing. (8 Days)

Arranged public service announcements on child immunizations - played on 16 radio stations. (3 Days)

*Implementation Problems.....*

In addition to obtaining quantitative data on the agencies' actual performance, this survey elicited a wide range of agency comments regarding either their accomplishments or their disappointments and frustrations, mostly the latter. As much of the summary above deals with accomplishments, this segment will deal only with the reported "problems":

There were many complaints regarding HEW's performance in administering the law, e.g.,

"There are a lot of deadlines imposed upon the HSAs while deadlines for federal actions are allowed to slip continuously. Agencies that develop early find themselves being used rather than helped."

Problems directly connected to federal policies also included concern about the emphasis "solely" on cost containment. This was particularly a factor with HSAs in areas which report that their areas are already under the national average on beds, hospital costs, etc., and remain significantly medically underserved in every respect. They felt that the attention to cost control and system shrinkage will cause them to be ignored and even given low marks on performance.

Another set of frustrations were directed at state government. For instance, a few HSAs expressed concern that the SHPDA "overturned" the HSA decision "indefensibly". Several states were accused of buckling under political pressure, vitiating volunteer and staff willingness to stick to an already tough job. (Sometimes, though, the criticisms ran the other way: SHPDAs accusing HSAs of being unwilling to make the "tough decisions", leaving them up to the state to handle.)

A not unrelated complaint frequently expressed was that CON/1122 applicants have more resources at their disposal than the HSAs and can bring in experts and sophisticated legal counsel to buttress their case. The "unfairness" of this practice being a reimbursable expense under public financing programs was mentioned. Increasing litigation, appeals or highly legalistic "public hearings" using a state hearing officer requires keeping records beyond what might be considered good practice, and using scarce resources for legal fees.

Finally, the problems afflicting the predominantly rural HSAs were emphasized by many respondents. The major problem cited was lack of adequate funding — these agencies get a minimal grant but are still required to meet all the statutory responsibilities of the typical HSA. Further, there are often vast distances, sparsely settled, which call for inordinately large expenses related to travel for staff, governing body members, and subarea council work. One agency had to spend 25% of its \$175,000 grant on travel alone because that HSA covers over 68,000 square miles (for comparison, note that the whole state of New York is not quite 50,000 square miles).

#### *Keeping the Results in Perspective....*

The most difficult aspect of the survey's analytical challenge lies in trying to put all the pieces together to accurately depict the functioning of a young institution, the health planning agency. The tasks of that agency are enormous — to make our health care systems more rational, more understandable, more responsive to public needs and wants, more resource conserving and health promoting! As a result of the HSA/SHPDA work, our health care systems, as community-wide systems, should increasingly reflect the dynamics of a democracy (all affected parties participate, the majority decides) and the economic dynamics of a private enterprise (resources will be allocated to maximize health care returns on the investment dollar). To reach an acceptable level of tension between such diverse goals will take time, experience, patience and a willingness to recognize the realities involved. To evaluate our progress in all those directions will take more intelligence than the full results of this survey will provide. The next report from this survey, with results more fully analyzed, will provide useful, necessary, but not sufficient data to answer the public policy questions regarding the full value of the health planning program.

Questions and suggestions concerning the results to date are encouraged, and should be addressed to Harry P. Cain II, Ph.D., Executive Director, American Health Planning Association, 1601 Connecticut Avenue, N.W., Suite 700, Washington, D.C., 20009.

Second Report on the 1978 Survey of Health Planning Agencies

February 1979

I. Introduction.

This report summarizes the results of a Survey of Health Planning Agencies conducted in September, 1978. A preliminary report on selected aggregate statistics pertaining to project review under Certificate of Need and Section 1122 was released and widely distributed on November 28, 1978. This constitutes the second report on the 1978 survey and covers both project review activity and other facets of the planning agencies' performance from mid-1976 to mid-1978. With modifications based on this survey, the AHPA has begun a 1979 survey covering the planning agencies' performance during the last six months (July 1, 1978 to January 1, 1979).

This second report expands on the preliminary report in several respects. First, more agencies' responses have been abstracted and included in the analyses. Second, in this report we add the results from other parts of the survey (e.g., technical assistance activities). Third, more detailed breakdowns of data for all of the sections, including data from project reviews, are provided. We are not considering this the "final" report on the 1978 survey because several aspects of the performance data reported here require further analysis.

Purpose of the Survey

The 1978 survey was undertaken in September as a first step in an effort to collect, analyze and make public some reliable data regarding selected activities of the health planning agencies throughout the nation. In addition, the survey was intended to produce key statistics as benchmarks for building a more comprehensive information base for policy making at the national level.

There was no question about the need for the data we were requesting. The federal government has invested many millions of dollars in underwriting the development of health planning agencies. The states and localities have added more dollars to that investment, and many thousands of citizen volunteers have contributed literally millions of hours of effort to the successful establishment of the agencies -- to what end? Nationally there are no data, no reasonably objective, quantitative bases on which to evaluate the benefit from all that investment. That is the need to which the survey attempted to respond.

The emphasis in the survey is on performance data, not process data nor any other data needed to determine compliance with the multitudes of regulatory and legal requirements of the law. In every way possible, however, we have coordinated this effort with others, especially at the HEW Bureau of Health Planning, so data are compatible with their reporting requirements and can be examined and analyzed in a collaborative manner -- though no federal funds were used in the design or execution of the survey.

### Scope of the Survey

While asking for the proposed capital investment that planning agencies had reviewed under State Certificate of Need laws or under "1122 agreements" signed with the Secretary of HEW, and the cost consequences of the projects reviewed, the survey sought to determine whether capital costs were associated with beds, equipment or other changes in service and whether the expenditures were proposed for new services, renovation of existing capacity or other improvements.

There was also a particular interest in learning about and documenting two other facets of planning agencies' activities which can have major impact on the shape of the health care system, and have been least well known outside of the agencies themselves. These are 1) the provision of technical assistance to others in the community, particularly toward developing or strengthening needed projects, and 2) the dissuasive advice, or sometimes even a dissuasive atmosphere, that results in the non-submission or withdrawal of applications for unneeded projects. This latter activity has been cited repeatedly as one of the most significant and increasingly effective contributions of HSAs and SHPDAs, but it has been, and remains, quite difficult to document and evaluate. This survey makes a stride towards more understanding of those activities and how they might be measured in the future.

## II. Research Methods

The survey instrument called for some identifying and budgetary data to be reported on the agency and for selected information on 1) capital expenditures review under Section 1122 or under Certificate of Need, including presubmission actions which may have reduced costs or improved the system, 2) reviews of proposed uses of Federal funds, 3) the provision of technical assistance, and 4) accomplishments or problems not otherwise reported.

### A. Form A and A-1, Official and Unofficial Project Review Actions

There were two sections on the questionnaire concerned with capital investment and possible cost savings. The first Form (A) related to formal project reviews under CON or Section 1122. The second (A-1) attempted to draw out quantitative data on the potential impact of proposals not officially submitted or withdrawn because of HSA action or advice.

Included on Form A were only those projects officially reviewed under CON or 1122. Agencies were asked to identify projects by name, give the type or nature of project (beds, equipment, change in service), whether the project was for construction, purchase, conversion, etc.; and the dollars involved for capital investment and estimated annual operating costs. A large comments section for each project was available.

The second form (A-1) was intended to gather information on activities or actions which affected the CON or 1122 proposal prior to the official submission. In effect, the major difference between Forms A and A-1 was related to the time of action: all presubmission changes were to be reported on A-1; post submission (official) changes on Form A. The effect of this division of reporting may be confusing: e.g., if a hospital wanted to add 100 beds, at a cost of \$8,000,000, then, in informally discussing the idea with the HSA, decided to formally apply for only 20 beds at \$2,000,000, of which 15 beds and \$1.4 million were formally approved, the report would show:

	<u>reviewed</u>	<u>approved</u>
form A	20 beds, \$2 M	15 beds, \$1.4 M
form A-1	80 beds, \$6 M	-----
(Total	100 beds, \$8 M	15 beds, \$1.4 M)

Another source of confusion in the A and A-1 reporting is the categorization of the projects reported -- into a "hospital beds" proposal, or a "hospital renovation" proposal, or a "hospital equipment" proposal, etc. Many projects actually involved more than one type of proposal, but where the types and costs were not separable, they were coded into only one category. Hence the figures showing the results by category (Table C, below) are rough.

B. Form B, Proposed Use of Federal Funds (PUFF). Another subject addressed in the questionnaire concerned reviews for the proposed use of Federal Funds (bureaucratically dubbed PUFF). Agencies were asked to give a brief description of the project, the estimated costs of the program (operating and capital) and the Agency's action, although it was recognized that many of the agencies would not have begun doing project reviews for federal health fund applications at the time of the survey. In fact, technically they could not have been doing full-scale PUFF reviews both because they had not been given a go-ahead by HEW to do PUFF reviews, and HEW had not issued the required regulations.

C. Form C, Technical Assistance. A fourth form, C, reflected an interest in obtaining quantitative evidence of the amount and type of technical assistance provided to others in the community. The number of person days of staff time was suggested as a good indicator of resource investment and agencies were asked to list the technical assistance, its nature and outcome, if possible.

D. Form D, Other Accomplishments/Problems. Since a number of agencies had suggested in correspondence and expressed in some of their own reports, actions or accomplishments which did not fall into any of the first four categories but were important to document, we also asked for a summary of other achievements or disappointments. Agencies were asked to "note such frustrations as inadequacy of resources or too much litigation or inadequacies of CON law or such achievements as requiring nursing homes to agree to accept a minimum of 33% Medicaid patients for a CON."

Finally, there was a form E, also open ended, which asked for



criticisms of the reporting form and suggestions for modifications. Results of that will not be reported here; there were only a few responses, and they were incorporated into the new (1979) survey.

E. Editing, Validating and Abstracting. When the forms were received, the data were checked and an abstract form for the aggregate figures was completed. When there were questions, the individual named on the form for call-back purposes was contacted for clarification.

Three other methodological facts are worth noting here. First, proposals that were still "pending" in August, 1978, were not counted having been reviewed. They will be included in the second survey. Second, whenever a facility was transferred to or purchased by a person or a corporation with no change in service, programs, beds or capacity, the acquisition or transfer was not counted, even though there may have been some dollar figures associated with the transfer. This was done as long as there was no change in capacity to the health system. Third, whenever a project came into an agency for review more than once it was counted only as one review. For example, if a Hospital applied twice for a 50 bed expansion and \$2,000,000 worth of renovation, was turned down by the HSA both times, but later applied again for, and had approved, \$1.5 million worth of renovation, 10 new beds and an improvement in the Emergency Room, the HSA would be counted as reviewing only the first proposal, and would only get credit for costs savings of \$.5 million and 40 beds.

F. Some Methodological Problems. In addition to more routine or predictable problems associated with this survey, such as the difficulties accompanying the estimation of operating costs connected to each capital investment, there were three significant methodological problems which affect the meaning of these data and should be kept in mind by the reader.

First, it is not at all clear what effect there is on potential applicants when they are confronted by a tough regulatory environment and/or there is a well developed Health Systems Plan. One would assume that if in a particular state or area it is well known that no new hospital beds are likely to be approved, it is unlikely that hospitals will apply for approval of new beds. Like a strong defense posture, the deterrent effect of a solid or outstanding program is not possible to prove, but has intuitive appeal and there is considerable anecdotal evidence that capital investment in such an environment is at least shifted to other purchases if not halted. On the other hand, if it is known that only a few new beds will be approved, there may be a competitive scramble for the approval, resulting in more applications than one might otherwise have anticipated. In any event, the regulatory/planning ambience and its effects on behavior will never be quantifiable in a perfectly satisfactory manner; witness this statement from an HSA director who reported data on disapprovals and then followed with this statement:

"These disapprovals do not take into consideration those projects that have been discouraged by the Health Systems Agencies, based on the fact that their Health System Plans did not show a need for certain projects. Above the 13.5 million dollars that the HSA has actually disapproved, our agency can document another 12.5 million dollars that have been discouraged, prior to the applicant filing, simply because the Health Systems Plan shows that there is no need for these specific projects.

A similar phenomenon, as well as an example of how technical assistance by the agencies can improve the health system is captured in another letter from an HSA Director:

It should be emphasized that our HSA does much more than simply approve or disapprove capital expenditure proposals. We first seek to help the proponent of a project plan properly for a needed service. We help the applicant (provider) develop a proposal that is consistent with identified community needs. Most of the nursing home and home health care proposals developed in this area during the past four years are a result of this effort. As part of this "positive" planning process, as some like to call it, the HSA has discouraged or redirected substantially more applications (particularly for nursing homes, CT scanners and surgical centers) than it has disapproved. In most cases it is not possible to demonstrate this quantitatively. I believe it is fair to say, however, that this is where the HSA has been most successful. I am personally aware of projects and proposals for more than a dozen nursing homes, three CT scanners, three ESRD facilities, two proprietary hospitals, two proprietary free-standing surgical centers, and two proprietary "alcohol treatment centers" that have not pursued or developed because of HSA (and in some cases also SHPDA) policies, plans and analyses.

This was a theme echoed by many of the planning agencies, suggesting that their real value is difficult to measure because so much is connected to the reshaping of plans and projects in ways responsive to a community's needs (both unmet and overmet).

We saw in numerous instances that the simple recitation of numbers would fail to convey the nuances of the experiences being surveyed. Much of what the agencies do may involve significant changes in projects which may benefit everyone -- improve service and reduce costs -- but would not show up in the tables as a "disapproved" or dramatically reduced project. The second part of the following example submitted by an HSA Director (with corroborating evidence) illustrates this point:

In late 1976 an area hospital, (one of seven in our region), submitted an application for renovation and new construction at a total cost of \$15 million. The application was abruptly withdrawn when a newspaper reporter, covering HSA

activities, made an inquiry for further information. The hospital offered a recast version of its proposal a short time ago. The new price tag was \$10.5 million. We reviewed the proposal, and found that improvements were needed as indicated, in surgery, emergency, laboratory, and other hospital departments. Because the project involved extensive new construction, we acquired the services of an architect to give us a "second opinion" on the design and engineering features. We were assured that the hospital could not achieve its objectives at a lower capital cost.

On the other hand, our review uncovered certain problems. The hospital had an excess of licensed bed capacity; it had projected a minimal percentage (6%) of ambulatory surgery; its emergency room was found to be excessively used by patients seeking primary care, and it was planning the purchase of expensive laboratory equipment without first exploring the possibility of sharing with a nearby hospital.

HSA approved the proposal with four conditions which sought to correct the above findings. The Rate-setting Agency responded to our concerns and negotiated directly with the Hospital for modifications prior to their agreement of need. The Hospital reduced its licensed beds from 426 to 306 (present staff capacity) and pledged to further reduce its staff beds by 20-30 within one year. A separate unit within the Emergency Room will be established to treat primary care patients at a lower cost. Ambulatory surgery will be increased to 20%, and discussions are under way with area hospitals.

The Hospital also pledged to strengthen its utilization review procedures and to reduce its average length of stay from 8.4 to 6.9 days.

The Rate-setting Agency noted that with these modifications, the Hospital's operating budget would be reduced by \$509,000 annually by 1982. A further reduction of \$240,000 - \$318,000 can be achieved by closing of 20-30 additional beds within one year.

The second methodological problem which influences the meaning of the data can be stated as an elaboration of the "competitive effect" noted above. The disapproval of a particular investment, especially beds, keeps the investment potential open in a way that the approval of the investment by the agency may not. For example, a planning agency may have turned down five requests, each for 200 nursing beds, but if the agency had accepted the first request for 200, there may have been no more requests. In other words, if the HSA turned down the first five requests, but approved the sixth, it may actually have prevented or "saved" nothing, or it may have prevented the building of 1000 unneeded beds and "saved" the costs associated therewith, or (most likely) the real savings are somewhere between nothing and the cost of 1000 beds!\*

\*Where it was apparent that several applications were "competing" for only one likely approval (e.g., a sequence of CAT scanner proposals from the same hospital or "competing hospitals" until one proposal was approved), we did not count the disapprovals as "savings".

Third, there are often extensive negotiations, as illustrated by the example on page 10, between an applicant and the planning agency resulting in significant cost saving changes over time, but very difficult to reflect in our survey instrument. In several places, for instance, we learned about improved financing at much lower interest rates obtained during HSA review. All of the system improvements cannot be easily documented or their cost savings quantified but they are happening and are important to bear in mind.

While there is no way to adequately correct for those three methodological problems, it is important to recognize them and make judgments and interpretations accordingly. At the very least, we should emphasize the meaningless of "approval rates".\* For some of the reasons cited above, one might predict a U-shaped curve in percentage of approvals. That is, a first-rate planning agency, with a well developed, highly publicized, resource-conserving plan and good community standing, could boast of a very high approval rate; and an ineffective HSA may also approve virtually all applications. The difference is in the nature of the applications and the community-wide planning which can document the need for the projects proposed.

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\* Note GAO report "Status of the Implementation of the National Health Planning and Resources Development Act of 1974," November 2, 1978; p. 28. The GAO report uses approval rates as the key indicator of project review experience.

ResultsIII. A. Areas and Agencies that Responded.

There are 207 health service areas in the 50 states and the District of Columbia: 204 served by HSAs/SHPDAs and 3 served by SHPDAs only (Rhode Island, D.C., and Hawaii).<sup>1\*</sup> The 166 HSAs (81%) and 27 SHPDAs (53%) that responded to this survey provide us with usable data on 171 of the 207 areas. With the more complete responses from the HSAs, we often used only the HSA data, or the HSA and the SHPDA data, at least regarding CON/1122 experience. The exceptions, where we used only SHPDA data, were Rhode Island (a 1536 state), Kentucky and Mississippi. In one instance, in California, we used SHPDA data to report the results of projects from one sub-state health service area (Los Angeles).

Because most of the non-respondents are located in the less heavily populated areas, the 171 covered areas account for 88% of the U.S. population.<sup>2\*</sup> Table A arrays all the HSAs by size of area, and shows the number of respondents in each size category.

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1\* The health planning program also covers six other areas -- Puerto Rico, the Virgin Islands, Guam, Samoa, the Trust Territories and the Northern Mariana Islands, -- but they are not included in this report.

2\* Actually, with more analytic resources we could pull data on another 18 HSAs from the data submitted by the SHPDAs; if and when we do that, 95% of the U.S. population will be covered. Attachment A shows the agencies that responded. The seventeen areas on which we have no data are:

New Hampshire  
 Connecticut HSA #4 (North Central Conn.)  
 Washington, D.C.  
 Tennessee HSA #1 (and Virginia HSA #6 = Appalachian Regional Center  
     for Health Advancement)  
 Alabama HSA #5 (Southeast Alabama)  
 Minnesota HSA #2 (HSA of Western Lake Superior)  
 Minnesota #5 (St. Paul)  
 Minnesota HSA #7 (Southeastern Minnesota)  
 Illinois HSA #9 (Kendall, Grundy, Will and Kankakee Counties)  
 Arkansas HSA #2 (Delta-Hills)  
 Missouri HSA #5 (Southeast Missouri)  
 North Dakota HSA #2 (Agassiz, includes Minnesota #1)  
 North Dakota HSA #3 (Min-Dak, includes Minnesota #3)  
 Nevada HSA #2 (Clark County)  
 Arizona HSA #2 (Southeastern Arizona)  
 Arizona HSA #3 (Northern Arizona COG)  
 Hawaii

Population of area	3.0 million & over	2.0-3.0 M	1.0-2.0 M	.5-1.0 M	.2-.5 M	less than .2 M	TOTAL
Total # of HSAs	5	15	48	87	44	5	204
# of responding HSAs	4	14	43	69	32	4	166
% responding	80%	93%	90%	79%	73%	80%	81%

TABLE A

Another indication of the breadth of our HSA respondents is reflected in this breakdown by region of the country:

Responses by Region

	<u>No. of HSAs</u>	<u>No. Responding (%)</u>
Region I (New England)	14	12 (86%)
II (New York - New Jersey)	13	12 (92%)
III (Mid-Atlantic)	20	18 (90%)
IV (Southeast)	40	31 (78%)
V (Upper Midwest)	42	36 (86%)
VI (Southwest)	21	18 (86%)
VII (Mid-west)	12	10 (83%)
VIII (Rocky Mts)	10	7 (70%)
IX (Calif., Ariz., Nev., Ha.)	21	11 (52%)
X (Pacific NW & Alaska)	<u>11</u>	<u>11 (100%)</u>
	204	166 (81%)

TABLE B

Finally, we did a breakdown of the HSAs into those that are essentially new agencies (i.e., created de novo under P.L. 93-641) and those that grew out of predecessor agencies (typically one or more CHP "b" agencies). Approximately 44% of the HSAs (90 out of 204) are considered "new", the rest "old". 79% of the "new" participated in the survey, 83% of the "old".

### III. B. CON/1122 Reviews.

During the two year period under study, the planning agencies "intervened" in at least \$12 billion worth of capital investment proposals. As a consequence of the intervention, \$3.5 billion were not invested.

Those overall results include the following subcomponents, as reflected in Table C, on the following page:

In the review of proposals from short term, acute care hospitals, the planning agencies officially considered 11,488 new beds and denied 3,648 (32%) of them. Another 4,292 proposed beds were never submitted for official review. As a result, in total, \$558.5 million were not invested in new beds.

During the same time, a much larger amount, \$4,698,300,000 were proposed for hospital renovations, much of which was aimed at bringing the facilities into compliance with various life and safety codes and other accrediting standards. Most of these proposals (\$4,428,200,000) were officially submitted, and most were approved. Only \$520,000,000 (11%) were denied, including \$195,500,000 that did not make it to the official application stage.

In clinical equipment, the agencies considered \$515,500,000 worth of proposals, of which 21% was denied (including 13% never officially submitted).

For long term care facilities, 113,883 new beds were proposed (84,692 of them officially requested), of which 48,666 (43%) were denied (including 23% of the official requests). The capital investment dollars "saved" as a result totaled \$718,900,000.

The figures reported in the "other" category (row 12) relate to such proposals as end stage renal disease centers, community mental health centers, ambulatory surgery centers, hospices, etc. \$548,800,000 worth of such proposals were considered, and a large percentage (34%) were dropped before becoming official applications. Of the \$383,200,000 formally submitted \$34,800,000 (9%) were disapproved.

TABLE C

Proposed Capital Investments Reviewed and Denied  
By Respondent Health Planning Agencies, 1976-78.

	PROPOSED (\$ in millions)			DENIED (\$ in millions)		
	UNOFFICIAL (1)	OFFICIAL (2)	TOTAL (3)	UNOFFICIAL (4)	OFFICIAL (5)	TOTAL (6)
<u>Hospital Investments</u>						
number of beds (1)	4503	11,488	15,991	4292	3648	7940
\$ in beds (2)	301.0	1,174.9	1,475.9	295.5	262.9	558.5
\$ in equipment (3)	69.7	445.8	515.5	68.4	37.5	105.9
\$ in renovations (4)	270.1	4,428.2	4,698.3	195.5	324.6	520.0
\$ in other (5)	13.5	361.0	374.5	13.5	31.8	45.3
\$ Total (6)	654.3	6,409.9	7,064.2	572.9	656.8	1,229.7
<u>Long-term Care (SF/ICF)</u>						
number of beds (7)	29191	84692	113,883	29191	19475	48,666
\$ in beds (8)	424.7	1,426.5	1,851.2	424.7	293.9	718.9
\$ in renovations (9)	12.9	206.4	219.3	10.2	16.2	26.3
\$ in other (10)	14.5	15.5	29.9	14.4	1.5	15.9
\$ Total (11)	452.1	1,648.4	2,100.4	449.3	311.6	761.1
<u>Other</u>						
(12)	202.3	383.2	585.6	200.6	34.8	235.3
Totals (13)	1,308.7	8,441.5	9,750.2	1,222.8	1,003.2	2,226.1
L.A. (14)		2,178.6	2,178.6		1,273.6	1,273.6
Totals (15)	1,308.7	10,620.1	11,928.8	1,222.8	2,276.8	3,449.7



"Operating Costs"

Although The survey asked for estimates of "annual operating costs" associated with each proposed capital investment project, we cannot report on the operating cost "savings" connected with the capital investment disapprovals. 58% of our respondents could not give us any of that data, 23% could give us operating cost estimates for some of their projects, and only 18% could give us such data on all their projects. The reasons for their inability to provide the data range from incomplete record keeping to State CON regulations that prohibit the agencies from asking for any data not required on the application form (forms which often do not ask for operating cost data). In any event, we can only make gross estimates of the operational costs saved by the denial of capital investments.

Our gross estimate would run as follows: if annual operating costs average 30% of the capital costs (a conservative estimate), then the operating cost savings for 1980, and for each year thereafter (at least through the 1980's) would be at least \$1 billion; or \$10 billion over the next decade.

"Investments Per Capita"

For all the agencies reporting, the amount of proposed capital investment reviewed per capita, for those 2 years, was \$78.50 (\$65.15 officially); the amount denied was \$26.45 (\$13.97 officially).

For comparative purposes, note that the amount invested in health planning per capita, for those two years, was \$1.69. That figure includes the costs of the HSAs, SHPDAs, Centers for Health Planning, and Federal "program support" costs.

In the sections to follow, we point out some characteristics of the data which should be kept in mind as the figures in Table C are read. In particular, we attempt to clarify the "period covered" by the review activities (it's not the full two years covered by the survey); the peculiarities of the Los Angeles data; the differences between "unofficial" and "official" reviews; the lack of tidiness in the categories (e.g., "beds" v. "renovation").

III. B. 1 Performance Period Covered.

The period of performance covered by the survey was two years, from August 1976 to August 1978. The only part of the survey where we must be precise regarding the period covered is the CON/1122 review performance period. Thus, it is important to note that many of the reporting agencies had not begun doing reviews by August, 1976, and some had not begun by August, 1978. The chart on the next page shows the cumulative number of the 166 reporting HSAs doing reviews during the two year period.

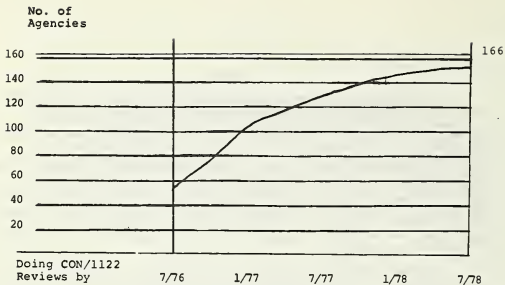


CHART A

As that chart suggests, about 20% of the two year period was "lost". That is, our project review performance data covers only 80% of the time that would have been covered if all 166 agencies had been doing reviews from July, 1976 onward. However, the volume of project reviews over the 2 year period was somewhat larger than the chart would suggest because the agencies that began at the later dates tend to be smaller agencies. Of the 34 HSAs that began reviews after July, 1977, all served areas of less than two million population, and most (23) served areas of less than one million population.

Table D arrays the 166 reporting agencies by size and "age of reviewing process".

POPULATION OF REPORTING HSA AREAS

	3.0 million & over	2.0-3.0 M	1.0-2.0 M	.5-1.0 M	.2-.5 M	less than .2 M	TOTAL	CUMULATIVE TOTAL
Began reviews:								
before 7/76	1	3	17	25	12		58	58
7/76 - 1/77	1	7	12	23	8	1	52	110
1/77 - 7/77	2	2	3	8	5	2	22	132
7/77 - 1/78			5	5	1		11	143
1/78 - 7/78			3	5	3	1	12	155
after 7/78		2	3	3	3		11	166
TOTAL	4	14	43	69	32	4	166	
CUMULATIVE TOTAL	4	18	61	130	162	166		

TABLE D

Given that weighting factor, we can estimate that approximately 15% of the two year period was not used for reviewing by the 166 agencies. Making adjustments for the other five areas also covered by this report (from non-HSA data), we can modify the statement made above, that 88% of the population is covered by this report. In fact, we are reporting on the CON/1122 experience, for 1976-78, for approximately 75% of the U.S. population. Moreover, as we explain below, our data are that comprehensive only on "official" review actions.

### III. B. 2 Los Angeles.

Until the middle of last month (January) we had assumed that our final tally would not include the Los Angeles area. Not only had the HSA for Los Angeles County been terminated, but even when it was operating it had not been doing CON reviews. The California SHPDA had been doing all reviews for the Los Angeles area, and although the SHPDA had responded to our survey, and did break their data down by HSA area, their data did not go beyond September, 1977. Hence, we did not use it.

Then we discovered that a consulting firm (Siegel and Associates, Orinda, California) had done a study of the state CON records, for two years from July, 1976 to July, 1978, focused entirely on Los Angeles County. With the help of staff of the Health Insurance Association of America we have seen the results of that study and included them in this report -- but separately identified (in Table C, Row 14).

We show the Los Angeles data separately because (a) the magnitude of the figures could distort the rest of the national picture, and (b) the figures are not broken down into our sub-categories. Over that two year period, \$2.4 billion in Los Angeles proposals were submitted: \$1.27 billion were disapproved, \$900 million approved, with \$230 still pending.

It is important to remember that this period covers the beginning of the new California CON law (which provided for, among other things, certificates of exemption -- COEs -- from the CON program). 93% of the \$2.4 billion in application were for COEs! 98% of the approvals were for COEs. To quote from the consultants report:

"of the COEs, 68 percent were approved under the provision of Sec. 437.11a -- applicants claiming substantial economic loss if denied -- and 22 percent were approved under 1268 -- projects with prior approval from a valid area health planning agency review."

### III. B. 3 "Unofficial" v. "Official":

As described in Section II A, above, the agencies were asked to report not only the "official" reviews of CON/1122 applications, but also the "unofficial" (but documentable) pre-application "reviews" which resulted in a project either being dropped, or changed in scope before submission for official review. While 93% of the responding agencies completed Form A, on official reviews, (the remaining 7% not having begun CON/1122 reviews), only 60% were able to complete Form A-1, on "unofficial reviews". Many agencies do not keep records on "unofficial" activities. The first caveat, then, is that these data probably "under-report" the amount of unofficial action on the part of the agencies.

The second point to emphasize is that the agencies that did keep records on unofficial actions actually reviewed much more than is shown

in column (1) of Table C; column (1) is an artifact of our reporting instructions. For example, suppose a hospital had a pre-application meeting with the HSA, discussed its proposal for a 50-bed expansion, and learned that the HSP/AIP will only call for another 17 beds in that hospital's service area; subsequently the hospital officially applies for a CON for 22 beds. The data would then be reported under "unofficial" as 28 beds reviewed and dropped (denied). "Officially" the data would be reported as 22 beds applied for, with 17 approved (i.e., 5 denied).

In some rows, e.g., in the "number of beds" for hospitals (row 1), there are small differences between the figures in columns (1) and (4). Those differences may be due to agency failure to perfectly separate out of column (1) all the figures that should have been reported in column (2), or they may reflect unofficial considerations that are still "pending" (i.e., no decision has been made), or they could simply reflect abstracting errors on our part.

### III. B. 4 Beds v. Equipment v. Renovation, etc.

Another caveat relates to the subcategories used under both "hospital investments" and "long term care" headings. Many projects included proposals in more than one subcategory, but were not able to be broken apart in our abstracting. These projects were then attributed to one subcategory or another, depending on what appeared to be the largest single component in the project. In these cases, the reporting agency was called for clarification, but often the details were not available due to the passage of time, staff turnover, etc.

The "cleanest" category was "hospital equipment", as the figures for clinical equipment proposals were the most easily separated from other subcategories. Non-clinical equipment was put into the "other-hospital" category, row (5).

The most troublesome differentiation was between dollars for beds and dollars for renovation. While the figures in rows (2), (4), (8), and (9) are of the right order of magnitude, if precision is important they would be more safely considered together, i.e., (2 and 4) and (8 and 9).

### III. C. Proposed Use of Federal Funds.

Only 65% of the responding agencies completed this part of the survey. Mostly due to timing, this question did not elicit as much useful information as would have been desirable. The proposed use of federal funds review will be an important responsibility of the HSAs but, for reasons cited in II B, above, for many agencies it was not a major activity during 1976-78.

Depending on the agency, we got one of two responses to this item:

1. We have not started reviews under the Proposed Use of Federal Funds either because the agency has not been fully designated and did not have to review until such time or reviews could not be done officially until regulations are issued, and they have not been issued yet;
2. The agency has been doing "review and comment" and provided a detailed listing.

With limited staff and no access to computer capability the data we did have proved to be very difficult to analyze. We may at some later time code, group and abstract the data have on these activities, but probably will await the results of the next survey when the agencies will have more to report.

The volume and the type of activities that HSAs are involved in under PUFF is suggested in the following list of projects considered by one HSA. Our only editorial changes in this report were designed to protect the identity of the HSA. While we had more than 100 HSAs' reports on PUFF reviews, this one gives the flavor of the others' reported activities.

In many cases, it is not possible to tell either the reasons for a proposal's being approved or denied, or what finally happened to the project (i.e., what was the final Federal decision re the funding of the project). Nonetheless, the list does indicate both the kinds of projects considered and the kinds of action taken by the HSA. (The list runs for 7 pages, so we include only the front page here; the others are found in Appendix B.)

22

CASE EXAMPLEFAR WEST HSA

(POPULATION APPROX. 1,200,000)

Proposed Use of Federal Funds Review

Began Reviews: March, 1977

PROJECT SUMMARY	DATE REVIEWED AND HSA RECOMMENDED ACTION
1. Develop a comprehensive emergency and critical care system, \$1,059,580	7/9/77 Denial
2. Establish a mobile training program for education of emergency room nurses, licensed vocational nurses, and nurse trainees in various aspects of emergency medical care throughout County, \$84,630	7/9/77 Endorsed with following conditions: 1. That applicant provide evidence of State Certification concerning the proposed training course; and, 2. That applicant secure letters from at least 10 acute hospitals in County.
3. Continue to provide comprehensive mental health services to Catchment Area, \$490,105	7/9/77 Endorsed with comment: 1. That the applicant establish a better liaison with the community.
4. Establish a mobile Emergency Medical Technician training program in the reservation and offer a State Dept. of Health approved EMT-1A training program to a group of 15 Indians, \$32,120	7/9/77 Denial
5. Establish a primary care system, \$197,417	7/9/77 Endorsed with comment: That applicant provide IC/HSA with a copy of its revised budget
6. Continue the program by which low-income families receive medical care on a prepaid basis through membership in an HMO, \$825,744	7/9/77 Endorsed

### III. D. Technical Assistance.

Technical assistance is one of the several functions which planning agencies perform and often cite as among their most important. While not easily quantifiable, technical assistance is seen as one of their more useful and cost conserving activities. In this survey, we tried to obtain data on the kinds of technical assistance which agencies provide to the community and also get some measures of how much staff time those efforts involved. On the form (C) itself, the nature of technical assistance provided (and outcome, if possible) were requested; the example given was, "Provided leadership and technical support for three hospitals to share computer services -- after six months, agreement signed." A second column on the form was headed "Person days given within a 24 month period ending August 1, 1978 (e.g., 20 days senior staff time)."

One hundred twenty eight (128) HSAs (77%) and ten (10) SHPDAs answered this question, although many of those gave very general answers such as "all of our staff members give technical assistance to community groups, individuals and institutions for at least 20 percent of the time" or "while we give a lot of technical assistance, we do not keep any records of it." Some agencies mentioned that they had records and notes which reflected the technical assistance given but the records were kept in the individual project files and thus were not retrievable. A number of respondents expressed an intent to keep technical assistance logs for future use in analyzing their own actions.

#### Results:

Not only were many of the answers general, those which were specific were difficult to group in any meaningful way. Rather than attempt to do that and imply that a more systematic analysis than was possible was done, we will try to give some impressions and a sample of materials submitted to convey the flavor of the reports.

Technical assistance listings from agencies from several areas of the country -- the Northeast, the South, the Midwest, the Far West -- are provided below. A few generalizations can be made from all of the information reported. First, HSAs provide a wide range of different kinds of service, from help with writing grant applications to program planning for many different kinds of agencies and institutions. The recipients are mostly hospitals, health centers, health departments, etc., but also to consulting firms, research organizations, and a wide array of individuals and health groups.

Second, the work with recruitment of physicians, defining or interpreting data for designation of subareas as medically underserved or health manpower shortage areas is substantial and is not confined to predominantly rural areas. Counties within "urban" HSAs are often "rural" and medically underserved, so an HSA in an otherwise highly urbanized area may also have such developmental work.



Third, there is a catalytic role being played by HSAs to stimulate regionalization of services, sharing of services, between two institutions to raise consciousness about health education, health promotion, teenage pregnancy and a whole range of topics.

Fourth, very specific "needs assessment" work, particularly for long term care facilities or programs were noted by a number of agencies.

The unedited (except to protect identity) listings will give the reader the best picture of some of the data reported. While these are not representative in a statistical sense, they are good examples and appear not to be atypical. Four pages are included here, the rest in Appendix C.

A NORTHEAST HSA

( POPULATION APPROX. 1,700,000)

TECHNICAL ASSISTANCE RECORD

NATURE OF TECHNICAL ASSISTANCE PROVIDED	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
1. Advice regarding proposed merger of two hospitals.	15 days, Sr. Staff
2. Assistance in designation of health manpower short- age areas and potential placement of National Health Service Corps physicians -- Corps physicians in place. Recruitment going forward.	15 days, Sr. Staff 20 days, Jr. Staff
3. Assistance in development of HMO -- physician recruitment for individual practice association is underway.	5 days, Sr. Staff
4. Advice and information regarding development of a neighborhood health center -- grant request sub- mitted 9/78.	3 days, Sr. Staff
5. Data collection, analysis and dissemination per- taining to several projects undertaken by outside organizations -- for example, medical school study of hospital consolidation -- 6/77.	35 days, Sr. Staff 10 days, Jr. Staff
6. Preparation of an application for designation of a primary care health manpower shortage area in one County -- area has received designation.	5 days, Sr. Staff 5 days, Jr. Staff
7. Assistance in preparation of family planning pro- posal for one County -- family planning clinic opened.	5 days, Sr. Staff 15 days, Jr. Staff
8. Advice on the development of a proposal to provide migrant health services in one County.	10 days, Jr. Staff
9. Assistance in establishment of a nutrition program for women, infants and children.	10 days, Jr. Staff
10. Assistance in preparation of a County hypertension program.	10 days, Jr. Staff
11. Assistance in preparation of an Allied Health Para- professional Training Program -- application is in review cycle.	10 days, Sr. Staff
12. Assisted in development of the programs for youth health education conferences -- conferences held 1976, 1977, 1978.	10 days, Sr. Staff
13. Provided input regarding use of social services for health under Title XX -- April, 1978.	3 days, Sr. Staff
14. Provided assistance in design of County-wide Health Survey -- survey now underway.	10 days, Sr. Staff 10 days, Jr. Staff

A SOUTHERN WSA

(POPULATION APPROX. 800,000)

TECHNICAL ASSISTANCE RECORD

NATURE OF TECHNICAL ASSISTANCE PROVIDED	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
1. Assist applicants with the development of 1122 and Federal Grant Applications. On the average, work with two applicants per month with 1 day spent per applicant.	19 Months for Review x2 Days Per Mo. 38 Days, Sr. Staff
2. Organized community and provided technical support for Rural Health Initiative Planning Grants - three funded, one pending.	22 Days
3. Organized community and provided technical support for Rural Health Initiative Operational Grant - pending.	17 Days
4. Provided technical assistance and consultation to four community organizations for preventive/primary health care projects -- three funded, one pending.	9 Days
5. Assisted in recruitment of physicians for two medically underserved counties - two physicians now practicing.	8 Days
6. Assisted in recruitment of dentists for three medically underserved counties - two dentists now practicing, one moving soon.	4 Days
7. Provided leadership and technical assistance for nine home health providers to establish shared training program for staff - postponed.	7 Days
8. Provided technical assistance to eight hospitals in physician recruitment, arranged travel and interview schedules for visiting physicians.	5 Days
9. Provided technical assistance/consultation to eight community organizations in physician recruitment.	7 Days
10. Provided consultation and information to 27 community organizations regarding resource availability.	8 Days
11. Assisted location of one dentist in medically underserved county by seeking shortage area designation for loan repayment obligation on part of dentist - dentist now practicing.	1 Day
12. Negotiated MOU with U.S. Army Hospital for information exchange on manpower planning and health services impact on private sector near military installation - agreement signed.	2 Days

## A MIDWEST HSA

TECHNICAL ASSISTANCE RECORD

NATURE OF TECNICAL ASSISTANCE	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
1. Provided technical assistance to municipal hospital to establish an ambulatory care center in conjunction with a health promotion program. Results to date include: 1) agreements made by two physicians to staff a primary care center which will be operated by a health service network; 2) tentative commitment from Blue Cross to provide grant support for the development of a demonstration health promotion program; and 3) commitment from Board of Trustees of hospital to reduce the facility's inpatient bed capacity.	130 Days
2. Provided professional advice and consultation to physician's assistant training program.	15 Days
3. Helped establish, and acted as initial director for multi-site primary care network. Outcome: the operationalization of a \$500,000/year rural primary care program.	60 Days
4. Professional consultation on the scope and role of a University Geriatrics program. Outcome: Geriatrics Coordinator established in medical school.	5 Days
5. Participated in the development of a Health Services Research program at local medical school. Outcome: Basic Health Service Research program was initiated in October, 1978.	15 Days
6. Professional consultation for the development of an area health education center. Outcome: AAEC funded in October, 1978.	20 Days
7. Consultation to approximately 20 organizations concerning funding possibilities for their programs.	20 Days
8. Professional advisement and liaison with third party reimbursers, for hospital with financial difficulties. Outcome: financial viability of the institution was improved.	10 Days
9. Technical support to eight communities with limited primary care manpower. Outcome: All eight communities were designated as critical health manpower shortage areas. At least four physicians have been recruited.	30 Days
10. Provided technical support to complete feasibility study for neighborhood health center.	5 Days

A WESTERN HSA

(POPULATION APPROX. 1,300,000)

TECHNICAL ASSISTANCE RECORD

NATURE OF TECHNICAL ASSISTANCE PROVIDED	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
1. Assisted Health Services, Inc. in submitting a designation request to DHEW to have most of the high desert portions of area designated as dental underserved area. Request granted August, 1977.	25 Days
2. Assisted the Service Area, Inc. in submitted a designation request to DHEW to have area designated as a primary medical care manpower shortage area. Request granted February, 1978.	20 Days
3. Assisted in submission of designation request to DHEW to have area designated as medically underserved area. Awaiting decision.	25 Days
4. Provided leadership and direction to group establishing primary care clinic in area. Site, facility and director have been secured. Facility undergoing remodeling and physicians are being recruited.	20 Days
5. Provided assistance to two separate interested parties in plans and efforts to secure approval for establishing Intermediate Care facilities for developmentally disabled patients in HSA. Significance of this accomplishment is, despite dire need for inpatient nursing programs for D.D. patients and despite no state adopted planning methodology to meet needs of these patients, HSA was successful in convincing State Health Dept. of need for the two facilities.	25 Days
6. Provided assistance to state Health Manpower Policy commission in designating medically underserved areas. Designation was approved January, 1978.	5 Days

### III. E. Other Accomplishments/Achievements/Disappointments.

On the last page of the questionnaire agencies were asked to summarize any particular achievements or problems which were not included in previous sections. This was a residual category for information on "accomplishments," since much of the true flavor of the agency's "successes" were already reflected in the section on Technical Assistance discussed earlier. As there were no other invitations on the form for reporting frustrations or problems, this item was in practice used to indicate more negative aspects of the agency's experience.

Less than half of the agencies provided any additional information under this item on the questionnaire. Those who did cited one or two examples of achievements but reported more sources of frustrations which they believe impede their effectiveness. Many of the comments, especially the problems, were also echoed in cover letters from executive directors of agencies.

Achievements. A number of the respondents who answered this question cited specific, successful agency initiatives. For example, several HSAs noted their use of particular policies attached to project review decisions, such as:

1. limiting modernization/renovation projects only to hospitals with non-conforming beds;
2. requiring long term care facilities to accept a certain (e.g., 35%) percentage of Medicaid patients as a condition of approval.
3. requiring long term care facilities to develop outpatient care services such as day care to keep down the unnecessary use of inpatient beds.

Other frequently listed achievements included rural health initiative projects, work on recruitment for physicians, work toward obtaining mental health centers and a regional immunization day (e.g., 15 sites with 2,000 shots given in one day, without counting increases in use of private physicians as a consequence.) A substantial number of agencies listed conferences/workshops and seminars which they sponsored. Typically these were on such topics as:

- \* health promotion
- \* teenage pregnancy
- \* regionalization of services for prenatal care

Efforts to inform and involve business and industry and consumers were also mentioned.

When not reported on other sections of the form, several agencies reported convincing project sponsors to obtain much lower interest rates by shifting to tax exempt bonds for financing. Others indicated cases

in which the HSA had produced: (a) the first report ever on minority health problems in their area which had a significant underserved minority population (another did the first such report on minorities and low income); (b) for the first time, gaining productive working relationships with PHS hospitals and the military facilities.

The range of subjects and tactics used by HSAs is portrayed by the following case:

The HSA supported the state's "Association for Retarded Citizens" (ARC) in its request for a reconsideration hearing of the SHPDA's issuance of a Certificate of Need. The project involved the establishment of a 120 bed MR facility in a former nursing home building. HSA staff and the ARC maintained the project was not consistent with recent state legislation aimed at depopulating state mental retardation training centers and diverting other MR clients to alternative community placement. Based on testimony at the reconsideration hearing and subsequent analysis, the SHPDA rescinded the CON. The fair hearing which was offered was not accepted and the project was dropped. The HSA has helped with other alternative projects consistent with state policy.

Disappointments. Some of the more common frustrations reported concerned HEW's slowness in issuing regulations and guidelines. The agencies asserted that the absence of regulations hobbled their ability to organize and act in the mandated functional areas. In particular, continued delays in issuing regulations for Appropriateness Review and Proposed Use of Federal Funds (PUFF) Reviews were mentioned. One Director said it most dramatically: "There are a lot of deadlines imposed upon the HSAs while deadline for federal actions are allowed to slip continuously. Agencies that develop early find themselves being used rather than helped."

Some of the complaints were accompanied by reference to inconsistencies in the federal policies which were promulgated and changes in policies (both in the planning program and others which interface with planning), though specific examples of either inconsistencies or changes were not given.

Problems directly connected to federal policies also included concern about the emphasis "solely" on cost containment. This was particularly a factor with HSAs in areas which report that their areas are already under the national average on beds, hospital costs, etc. and remain significantly medically underserved in every respect. They felt that the attention to cost control and system shrinkage will cause them to be ignored and even given low marks on performance. They fear that the HSAs will be judged as ineffective even if the criteria are, by everyone's admission, totally inappropriate to their circumstances. (While given several ways to report their experiences, even this survey gave disproportionate weight to cost control interests, a fact that more than one agency reminded us of.)

The problem of inadequate funding especially from the minimally funded agencies was frequently noted, especially by agencies serving large geographic areas.

The lack of developmental funds to facilitate or accelerate the implementation of priority projects in the Health Systems Plan was also mentioned a number of times. Again, the rural HSA felt this most keenly.

While these problems were noted frequently, other ones were mentioned only by one or two. For example, one respondent lamented that, "Representatives of the federal government paint a simplistic picture about potential federal funds for services which is misleading and which must be overcome in the HSA (review) process."

Another reported that the HSA is not told by HEW about its funding decisions even after the HSA has spent considerable time doing reviews and working with the applicants.

The method of developing the National Guidelines also came under fire. One Director wrote that the guidelines "produced a great deal more opposition locally and demanded much more staff and volunteer time reacting to them than should have been necessary. Their hasty and uncoordinated development hurt the image of health planning nationally and locally."

Frustrations from problems at the state level were also cited by HSAs. For instance, a few HSAs expressed concern that the SHPDA "overturned" the HSA decision in a couple of totally unambiguous situations. Several states were accused of buckling under political pressure, vitiating volunteer and staff willingness to stick to an already tough job.

One SHPDA director in a State having only an 1122 agreement (without a CON law), volunteered this:

"One major concern ought to be not what was reviewed, but what happened after the review. In (this area), public fair hearing and court actions have allowed all but one eight-bed nursing home addition to proceed. The eight beds will be contested in court soon. These reversals of the DPA findings and recommendations amount to at least \$28,000,000 on one hospital project alone.

"CON and Section 1122 reviews are practically valueless without strong legislative support to prevent unneeded projects. As long as the applicant can appeal to hearing officers, regional D/HEW offices, D/HEW Washington, State courts and Federal courts, the DPA findings are no more than simply editorials.

"At this time, regional D/HEW offices and D/HEW Washington cannot reverse a hearing officer's decision even if others appeal for reconsiderations.

"To deny a project generally does not stop that project."

In general, a number of states, according to the HSAs, substantially delayed passage of CON legislation or passed a bill which has many problems in it for HSAs such as being out of compliance with federal requirements. An extraordinarily long delay on SHCC establishment in one state was seen as evidence of state animosity, according to one HSA.



There are other difficulties. One CON law allows only approval or disapproval as submitted. Conditions may not be attached to the approval; nor can most of the proposal be approved and one part (possibly minor) be disapproved. This limitation prolongs the process, increases "paperwork," staff time, etc.

#### General Frustrations.

Several other problems not specifically blamed on either state or federal levels were mentioned. For example, agencies complained that CON/1122 applicants have more resources at their disposal than the HSAs and can bring in experts and sophisticated legal counsel to buttress their case. The "unfairness" of this practice being a reimbursable expense under public financing programs was mentioned. Increasing litigation, appeals, or highly legalistic "public hearings" using a state hearing officer require growing attention to keeping careful records and using resources for legal fees. One routine public hearing held for CON applications, and considered duplicative by the HSA, took six full working days at the hearing alone, in a distant city. The costs for legal counsel in such instances are prohibitive.

Another agency described some of the special problems in an area which had never had a planning agency. The really "new" planning agencies do not have a body of volunteer or staff experience to tap and build on, nor does the agency have the most fundamental sets of data to get started with. On the other hand, HSAs which were created out of several former CHP (b) and/or RMP agencies might counter that trying to achieve consensus around one agency when there are well-developed, disparate forces and constituencies, and perhaps even long-standing animosities, is even tougher.

#### Rural Areas.

While mentioned in several different locations in this report, the special problems of rural agencies should be discussed and summarized separately.

A major problem is that funding - tied as it is to a population-based formula - is often the minimum amount or low in any event, while the agencies still have to meet all responsibilities. Further, there are often vast distances, sparsely settled, which call for inordinately large expenses related to travel to both for staff, governing body members, and sub-area council work. One agency had to spend 25% of its \$175,000 grant on travel alone because that HSA covers over 68,000 square miles (for comparison, note that the whole state of New York is not quite 50,000 square miles). The size of the health service area also means that sub-area councils are especially important. While helpful in many respects, sub-area councils also add some complications to decision-making.

Several agencies mentioned the special problems of high staff turnover, no trained pool of staff in the more remote areas, and the impediments to successful recruitment for such areas. For some, the emphasis on cost containment and looking at disapproval figures as measures of virtue were particularly unfair, as mentioned earlier. One HSA director wrote in a cover letter that his agency would not be

disapproving many projects because most major bed expansion is the culmination of years of prior planning to address unmet needs in an area which is significantly underserved in terms of medical care.

His state has hospital costs well below the national average, a bed to population ratio of 3.1 and an average length of stay of 5.5. Moreover, as a rural state with vast undeveloped pieces of land, "some decisions may look like duplication if one looks only at the population figures, but notable geographic barriers and travel time must be counted."

#### IV. Next Level of Analysis

Due to a shortage of resources, and the consequent need to manipulate these data by hand, there remain many levels of analysis untouched. One kind of analysis would compare HSAs with each other in a search for correlates of their review performance. For example, we should further break down the data by Region, by size of agency, by age of review process, etc. A second kind of analysis would compare HSAs performance with other indicators of change in their communities, such as the level and change in plant assets per short-term hospital bed. Further, we should link this second kind of analysis with the first, e.g., group the HSAs according to their current level of health care resources (for example, hospital beds per capita, employees per bed, specialized services available, etc.) and make inter-HSA comparisons with the same grouping in terms of their review performance, plan development, kinds of technical assistance provided, etc.

Finally, there are some "micro analyses" still to be done, e.g., regarding the treatment of HMOs or Hospices or ambulatory surgery centers, etc. Some of those analyses would also illuminate the effects of differences in State CON laws. We have not yet been able to control for, e.g., differences in CON scope and threshold of coverage. But doing these further levels of analysis, or running cross tabs on almost any combination of characteristics, will require automation of our data processing -- and, if resources are found, that's the next step.

#### V. Keeping the Results in Perspective:

In considering the results of this survey, we are impressed by the need to keep them in a rather broad perspective. The concerns we felt at the conclusion of the preliminary report have not decreased, so they are repeated here:

The most difficult aspect of the analytical challenge lies in trying to put all the pieces together to accurately depict the functioning of a young institution, the health planning agency. The

tasks of that agency are enormous -- to make our health care systems more rational, more understandable, more responsive to public needs and wants, more resource conserving and health promoting! As a result of the HSA/SHPDA work, our health care systems, as community-wide systems, should increasingly reflect the political dynamics of a democracy (all affected parties participate, the majority decides) and the economic dynamics of a private enterprise (resources will be allocated to maximize health care returns on the investment dollar). To reach an acceptable level of tension between such diverse goals will take time, experience, patience and willingness to recognize the realities involved. To evaluate our progress in all those directions will take more intelligence than the full results of this survey will provide, i.e., the next report from this survey, with results more fully analyzed, will provide useful, necessary, but not sufficient data to answer the public policy questions regarding the full value of the health planning program.

Questions and suggestions concerning the results to date are encouraged, and should be addressed to Harry P. Cain II, Ph.D., Executive Director, American Health Planning Association, 1601 Connecticut Avenue, N.W., Suite 700 Washington, D.C., 20009.

Appendix A

## HEALTH SYSTEMS AGENCIES BY STATE WHICH HAVE RESPONDED TO AHPA'S SURVEY

as of January 29, 1979

Alabama

North Alabama HSA  
 West Alabama Health Council, Inc.  
 Birmingham Regional HSA, Inc.  
 HSA Area IV  
 Southwest Alabama Health Planning Council

Alaska

Southeast Alaska HSA  
 South Central Health Planning and Development, Inc.  
 Northern Alaska Health Resources Association

Arizona

Central Arizona HSA  
 Navajo HSA  
 Western Arizona HSA

Arkansas

West Arkansas HSA, Inc.  
 Central Arkansas HSA, Inc.  
 South Arkansas HSA, Inc.

California

Northern California HSA  
 Alameda-Contra Costa HSA  
 Santa Clara County HSA  
 Mid-Coast HSA  
 Inland Counties HSA  
 Orange County Health Planning Council  
 Golden Empire HSA

Colorado

Southeastern Colorado HSA, Inc.  
 West Colorado HSA

Connecticut

Southwest Connecticut HSA  
 HSA of Eastern Connecticut, Inc.  
 Northwest Connecticut HSA  
 HSA of South Central Connecticut, Inc.

Delaware

Delaware Health Council, Inc.

Florida

Florida Panhandle HSA, Inc.  
 North Central Florida Health Planning Council, Inc.  
 HSA of Northeast Florida Area III, Inc.  
 Florida Gulf HSA, Inc.  
 South Central Florida Health System Council  
 Health Planning Council, Inc. (West Palm Beach)

(Florida - Continued)

Health Planning and Development Council for Broward County  
HSA of South Florida

Georgia

Appalachian Georgia HSA  
North Central Georgia HSA, Inc.  
East Central Georgia HSA, Inc.  
HSA of Central Georgia, Inc.  
Southwest Georgia HSA, Inc.

Idaho

Idaho HSA, Inc.

Illinois

Comprehensive Health Planning of Northwest Illinois, Inc.  
Illinois Central HSA  
West Central Illinois HSA, Inc.  
East Central Illinois HSA  
Comprehensive Health Planning in Southern Illinois, Inc.  
City of Chicago Commission for Health Planning and Resources  
Development  
Suburban Cook/Dupage HSA, Inc.  
HSA of Kane, Lake and McHenry Counties, Inc.  
Illowa HSA

Indiana

Northern Indiana HSA, Inc.  
Central Indiana HSA, Inc.  
Southern Indiana HSA, Inc.

Iowa

Iowa HSA

Kansas

Health Planning Association of Western Kansas, Inc.  
HSA of Southeast Kansas  
Northeast Kansas HSA

Louisiana

New Orleans Area/Bayou-River HSA, Inc.  
Mid-Louisiana HSA  
North Louisiana HSA, Inc.

Maine

Maine HSA, Inc.

Maryland

Western Maryland HSA  
 Central Maryland HSA  
 Health Planning Council of the Eastern Shore, Inc.

Massachusetts

Western Massachusetts Health Planning Council  
 Central Massachusetts HSA  
 Merrimack Valley Health Planning Council, Inc.  
 Health Planning Council for Greater Boston  
 Southeastern Massachusetts Health Planning and Development, Inc.  
 North Shore Health Planning Council

Michigan

Comprehensive Health Planning Council of Southeastern Michigan  
 Michigan Mid-South HSA, Inc.  
 Southwest Michigan HSA, Inc.  
 West Michigan HSA  
 Northern Michigan HSA  
 Upper Peninsula HSA

Minnesota

Central Minnesota HSA  
 Minnesota HSA Six

Mississippi

Mississippi HSA, Inc.

Missouri

Area II HSA of Missouri, Inc.  
 Mid-America HSA  
 Greater St. Louis HSA, Inc.  
 Southwest Missouri HSA

Montana

Montana HSA

Nebraska

Health Planning Council of Midlands

Nevada

Greater Nevada HSA

New Jersey

Bergen-Passaic HSA  
 Regional Health Planning Council  
 Hudson HSA  
 Central New Jersey Health Planning Council  
 Southern New Jersey HSA

New Mexico

New Mexico HSA

New York

HSA of Western New York, Inc.  
Fingerlakes HSA  
Central New York HSA  
HSA of Northeastern New York, Inc.  
Hudson Valley HSA  
Nassau-Suffolk HSA

North Carolina

Western North Carolina HSA  
Piedmont HSA, Inc.  
Southern Piedmont HSA  
Capital HSA, Inc.  
Cardinal HSA, Inc.  
Eastern Carolina HSA

North Dakota

Western North Dakota HSA, Inc.

Ohio

West Central Ohio HSA  
Health Planning and Resources Development Association of  
Central Ohio River Valley  
Miami Valley HSA, Inc.  
Health Planning Association of Northwest Ohio  
Mid-Ohio Health Planning Federation  
Area Six HSA, Inc.  
Health Planning and Development Council  
HSA for Summit-Portage County  
Metropolitan Health Planning Corporation  
HSA of Eastern Ohio

Oklahoma

Oklahoma HSA

Oregon

Northwest Oregon HSA  
Western Oregon HSA  
Eastern Oregon HSA

Pennsylvania

HSA of Southeastern Pennsylvania, Inc.  
Health Systems Council of Eastern Pennsylvania  
HSA of Northeastern Pennsylvania, Inc.  
Health Resources Planning and Development, Inc.  
Central Pennsylvania HSA, Inc.  
HSA of Southwestern Pennsylvania, Inc.  
Health Systems, Inc. of Northwestern Pennsylvania  
Keystone HSA

South Carolina

South Carolina Appalachian Health Council  
Three Rivers HSA, Inc.  
Pee Dee Regional HSA, Inc.  
Palmetto-Lowcountry HSA, Inc.

South Dakota

South Dakota HSA

Tennessee

East Tennessee Health Improvement Council, Inc.  
Georgia-Tennessee Regional Health Commission  
Middle Tennessee HSA, Inc.  
Mid-South Medical Center Council

Texas

Panhandle HSA  
South Plains Health Systems, Inc.  
Tri-Region HSA  
Texas Area 5 HSA, Inc.  
Central Texas HSA, Inc.  
Northeast Texas HSA, Inc.  
South Texas HSA  
Camino Real HSA, Inc.  
Greater East Texas HSA, Inc.  
Houston-Galveston Area Council HSA

Utah

Utah HSA

Vermont

Vermont Health Policy Corporation

Virginia

Northwestern Virginia HSA, Inc.  
HSA of Northern Virginia, Inc.  
Southwest Virginia HSA, Inc.  
Central Virginia HSA  
Eastern Virginia HSA

Washington

Puget Sound HSA  
Southwest Washington HSA  
Central Washington HSA  
Eastern Washington HSA

West Virginia

West Virginia HSA, Inc.



Wisconsin

Health Planning Council, Inc.  
Southeastern Wisconsin HSA, Inc.  
Lake Winnebago Area HSA  
Western Wisconsin HSA  
North Central Area Health Planning Association  
Northeastern Wisconsin HSA, Inc.,

Wyoming

Wyoming HSA, Inc.

State Health Planning and Development Agencies Which Have Responded as of  
January 29, 1979:

California	Tennessee
Colorado	* Texas
Florida	Wyoming
Georgia	
Idaho	
* Indiana	
Kansas (data submitted only through April 1978)	
Kentucky	
Louisiana	
Maryland	
Massachusetts	
Michigan	
Mississippi	
Montana	
Nebraska	
New Jersey	
New York (data submitted only through January 1978)	
North Carolina	
Oregon	
Pennsylvania	
Rhode Island	
South Carolina	
South Dakota	

\* Asterisk denoted agencies which have responded but did not or could not  
provide the information requested.

## APPENDIX B

## CASE EXAMPLE (CONTINUED)

FAR WEST HSA

PROJECT SUMMARY	DATE REVIEWED AND HSA RECOMMENDED ACTION
7. Project is designed to provide assistance to rural County Indian residents with mental health problems, \$105,000 (3-4 yrs.)	7/9/77 Endorsed
8. Continue establishing rural health clinics in County desert area and recruitment of medical manpower to meet health needs of area residents, \$697,108	7/9/77 Endorsed with comment that no future grant application will be endorsed of applicant is not present at project review meeting
9. Continue Family Planning Services in County, \$1,916,000	7/9/77 Endorsed
10. Continue efforts to establish a mental health center for County desert area, \$2,676,753	9/10/77 Endorsed with comments: 1. That applicant submit quarterly reports commencing 12/1/77, concerning progress of program, specifically applicant's efforts to recruit mental health professionals among ethnic and other minority populations; 2. That applicant increase efforts to involve community in planning and implementation of program and Board of Supervisors provide assurance that governing board is in compliance with membership matrix, developed in accordance with Federal guidelines; and 3. That in the absence of County's and State's ability to meet the mental health needs of rural area residents, applicant will institute a program which the county will need to carry out.
11. Develop and evaluate training program in nonverbal communication for physicians in order to increase physician's effectiveness and efficiency with patients, \$83,827	12/14/77 Denied

## CASE EXAMPLE (CONTINUED)

FAR WEST HSA

PROJECT SUMMARY	DATE REVIEWED AND HSA RECOMMENDED ACTION
12. Continue subject program designed to provide graduate training in Family Practice to doctors in a group practice setting, \$1,275,394	12/14/77 Endorsed
13. Plan, develop and operate a program for educational preparation of dental auxiliaries to be efficient members of dental care team performing legally delegated expanded functions under supervision of dentists, \$1,082,515	1/24/78 Endorsed
14. Provide mental health services to Catchment Area, \$1,657,611	4/27/78 Endorsed with comments: 1. That budget should reflect that applicant will provide at least 2% of yearly funds for program evaluation purposes. 2. That emergency services on a seven day week/24hr. basis be established by end of 1977-78 fiscal year. 3. That applicant implement formal plan for peer and utilization review of program.
15. Provide mental health services to Cathment Area, \$1,162,531	4/27/78 Endorsed with comments: 1. That vigorous efforts be taken to obtain transportation for patients; 2. That a more formal and adequate quality assurance program be documented; 3. That there should be more involvement of Citizens Advisory Council in the entire program, particularly review and comment of refunding application; 4. That the applicant submit copies of program progress reports to HSA that are regularly submitted to the funding source.

## CASE EXAMPLE (CONTINUED)

FAR WEST HSA

## PROJECT SUMMARY

DATE REVIEWED AND  
HSA RECOMMENDED ACTION

- | PROJECT SUMMARY                                                                                                                               | DATE REVIEWED AND<br>HSA RECOMMENDED ACTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16. Request for Rural Health Initiative funding to develop a primary care clinic, \$2,161,971                                                 | 4/27/78 Endorsed with comments:<br>1. That budget errors cited should be corrected and a revised copy submitted to HSA; 2. That applicant should submit quarterly and annual progress reports to HSA; 3. That applicant should work closely with the HSA Health Task Force in establishing clinic and applicant allow for ongoing input from the task force; 4. That the recommendation of approval is made on the assurance that the \$75,000 for the remodeling of the church building to be used as clinic, will be made available and that remodeling will be pursued expeditiously so that clinic may be in operation as soon as possible. |
| 17. Provide Family services through 20 clinic sites, \$1,039,484                                                                              | 4/27/78 Endorsed with comment:<br>1. That applicant submit quarterly progress reports to HSA to include, among other things, ethnic breakdown of staff, clientele served and Consumer Advisory Council and outreach efforts to rural areas and minority groups.                                                                                                                                                                                                                                                                                                                                                                                 |
| 18. Provide further expansion and continuation of present services which consist of pregnancy and youth counseling and education, \$2,023,212 | 4/27/78 Endorsed with comments:<br>1. That the applicant submit copies of letters of support for Family Planning Program from participating schools and other community organizations; 2. That the applicant submit quarterly progress reports to HSA.                                                                                                                                                                                                                                                                                                                                                                                          |

## CASE EXAMPLE (CONTINUED)

FAR WEST HSA

PROJECT SUMMARY	DATE REVIEWED AND HSA RECOMMENDED ACTION
19. Continue to make medical care available to low-income families living within a 30 air-mile radius of Medical Center to maintain enrollment of 1800 members, provide dental services to children and emergency dental services to adults, provide limited transportation services, provide health education services with emphasis on developing hypertension control program, to implement a Board of Directors, and to continue to administer the program as efficiently as possible, \$619,162	4/27/78 Endorsed
20. Continue to pursue goal of implementing a regional plan for coordinating and supplementing emergency medical services and training emergency service personnel within four counties, \$1,089,057	7/8/78 Denied
21. For further expansion and continuation of present services which consist of diagnostic, radiological treatment, emergency and preventative services and to establish additional service sites, \$560,924	7/8/78 Endorsed with comments: 1. The role of the Medical Director should be clarified, especially in the area of ongoing evaluation of quantity, quality and cost of provided services; 2. The applicant should provide copies of its Quarterly Reports to HSA; 3. The applicant should provide corrected figures for outreach to two towns in the 1978-79 Budget Assumptions; 4. The Applicant should provide a copy of Needs and Feasibility Study to HSA; 5. Evaluation procedures be developed for program.

## CASE EXAMPLE (CONTINUED)

FAR WEST HSA

PROJECT SUMMARY	DATE REVIEWED AND HSA RECOMMENDED ACTION
22. To establish a liaison between Indian and non-Indian mental health programs, \$103,650	7/8/78 Denied
23. Provide mental health services to Indians who reside on three reservations, \$91,200	7/8/78 Denied
24. Promote successful intergration of the chronic deaf of County into community through identification, information and consultation of the needs, abilities and potential of chronic deaf persons, \$84,708	7/8/78 Endorsed
25. Provide assertive behavior training to Spanish-speaking women in order to reduce the incidence of physical abuse, \$105,000	7/8/78 Denied
26. Conduct HMO Feasibility Study in County, \$91,467	8/9/78 No Recommendation
27. Conduct HMO Feasibility Study in (different) County, \$90,390	8/9/78 Endorsed
28. Conduct HMO Feasibility Study in four Counties, \$47,581	8/9/78 Endorsed with comments: 1. That the applicant study the feasibility of serving medically underserved areas; 2. That the applicant provide HSA with a complete final copy of the feasibility of study upon its completion.

## CASE EXAMPLE (CONTINUED)

FAR WEST HSA

PROJECT SUMMARY	DATE REVIEWED AND HSA RECOMMENDED ACTION
29. Provide comprehensive mental health services to Catchment Area \$3,372,768	8/9/78 Endorsed with Comments: 1. That the applicant submit quarterly reports to HSA describing its progress as of December 1, 1977, and, specifically, the applicant's efforts in recruiting mental health professionals among ethnic and minority populations; 2. That the applicant increase its efforts to involve the client community in the planning and implementation of the program and that the Mental Health Center Governing Board be brought into compliance with the membership matrix which was developed in accordance with Federal guidelines.
30. Provide Consultation and Education services to the residents and organizations of Catchment Area, \$65,844	9/9/78 Endorsed with comments: 1. That the applicant should provide a matrix of Citizens Advisory Council which will demonstrate representation for each of the geographical areas served by the Center, and document the selection process for Citizens Advisory Council membership; 2. That the applicant demonstrate that Consultation and Education Services are provided through the Catchment Area.



## APPENDIX C

A NORTHEAST HSA (CONTINUED)TECHNICAL ASSISTANCE RECORD

NATURE OF TECHNICAL ASSISTANCE PROVIDED	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
15. Provided assistance in development of feasibility studies for establishment of HMOs in two Counties - one not funded, other still in planning stages.	5 days, Sr. Staff 10 days, Jr. Staff
16. Consultation and data provided for medical school study of family practice location.	5 days, Sr. Staff
17. Leadership, consultation and data regarding merger of two hospitals in a large city -- new corporation formed.	20 days, Sr. Staff 10 days, Jr. Staff
18. Encouraged and provided technical support for applications for various mental health sponsors to establish intramural services -- for example, County Mental Health Department to implement AIP Objectives of day care program for mentally disabled; church home to establish alcoholism units.	20 days, Sr. Staff

A SOUTHERN HSATECHNICAL ASSISTANCE RECORD

NATURE OF TECHNICAL ASSISTANCE	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
13. Logged in total of 602 contracts on implementation/technical assistance matters.	11 Days
14. Provided technical assistance to one community organization seeking to establish an alcoholism treatment center for women - pending.	1 Day
15. Provided technical assistance to four communities seeking to fluoridate water supplies - not successful.	8 Days
16. Provided technical assistance to two health departments seeking to hire dental hygienists for education and treatment - funding arranged for one hygienist one pending.	2 Days
17. Provided technical assistance to three health departments seeking to hire additional VD investigators - not successful due to lack of funding.	2 Days
18. Provided technical assistance in development of 15-county EMS 1202-1203 grant application - funded or pending?	4 Days
19. Arranged public service announcements on child immunizations - played on 16 radio stations.	3 Days
20. Consulted with State Rural Health Program on development of four State-funded projects in the health service area.	3 Days
21. Coordinated technical assistance with State Rural Health Program on development of four projects in this health service area.	2 Days
22. Provided technical information on project grants to 13 home health providers in this health service area.	1 Day
23. Provided technical information to one private foundation consortium sponsoring primary health care projects in this health service area.	1 Day
24. Provided technical support to a Rural Health assistance group for community health projects organized and operated by students in graduate and professional schools.	2 Days
25. Provided technical assistance to another HSA in developing its Annual Implementation Plan.	2 Days

1. BUDGETARY DATATECHNICAL ASSISTANCE PROGRAMNAME OF TECHNICAL ASSISTANCE

PERIOD 1964-1965

MONTH 24 MONTH

PERIOD 1964-1965

15. TECHNICAL ASSISTANCE AND TECHNICAL SUPPORT TO SOLID  
 FUEL POWER INCLUDING (1) COMMUNITY REPRESENTATION  
 FOR DEVELOPING AGENCY AND (2) INFORMATION FILE.

16. COMPLETED UNIVERSITY OF HEALTH EDUCATION AND TRAINING  
 IN THE FOR DISSEMINATION OF PUBLIC HEALTH DATA FOR  
 IMPROVED HEALTH SERVICES BY COMMUNITARIAN.

54

A MIDWEST HSA

(POPULATION APPROX. 1,700,000)

TECHNICAL ASSISTANCE RECORD

NATURE OF TECHNICAL ASSISTANCE	PERSON DAYS GIVEN WITHIN 24 MONTH PERIOD ENDING 8/1/78
11. Provided technical assistance for five hospitals in filing 1122 and CON applications.	3 Days
12. Assisted Care Center preparing application for two critical health manpower shortage designation areas--one area now designated; other still under consideration.	50 Hours
13. Provide assistance to all applicants as requested.	30 Days (of Project Analysis)
14. Organized and conducted meetings with area radiologists to establish plan for future placement of CT scanners.	30 Days
15. Organized and conducted meetings with area obstetricians and pediatricians to establish area first Prenatal Plan.	40 Days
16. Provide technical support to two hospitals in the initial development of thier insitutions' long range plans.	5 Days
17. Organized area pathologists and hospital clinical chemists into a clinical laboratory task force to advise (us) on clinical laboratory matters - also resulted in an effort to have all area clinical laboratories accredited.	30 Days
18. Provide out-of-house technical assistance -- provide in-area residents, agencies and organizations and out-of-area agencies with whom data sharing agreements have been established or with whom cooperative relationships exist, with data, information and/or analysis and reports concerning population and demographics, economics, health status and health systems indicators utilization statistics and other aids such as references to data sources.	68 Days

Senator SCHWEIKER. Our next witness is Joyce C. Clifford, assistant director and director of nursing services, Beth Israel Hospital, Boston.

Ms. Clifford, I wonder if you would introduce the other members of the panel. Unfortunately, we do have a time problem, and since those of us hearing your testimony are supportive of your efforts, I would like to suggest that you summarize maybe for the group after you introduce them.

STATEMENT OF JOYCE C. CLIFFORD, R.N., DIRECTOR OF NURSING SERVICES, BETH ISRAEL HOSPITAL, BOSTON, MASS., ACCOMPANIED BY DORIS BLANEY, ED. D., R.N., MEMBER, ANA COMMISSION ON NURSING EDUCATION, AND PROFESSOR AND CHAIRPERSON, DIVISION OF NURSING, INDIANA UNIVERSITY NORTHWEST, GARY, IND.; LINDA K. AMOS, ED. D., FAAN, FOR AMERICAN ASSOCIATION OF COLLEGES OF NURSING, DEAN AND PROFESSOR, SCHOOL OF NURSING, BOSTON UNIVERSITY; ANNA B. COLES, PH. D., R.N., FOR NATIONAL LEAGUE OF NURSING, DEAN, COLLEGE OF NURSING, HOWARD UNIVERSITY; AND CONNIE BROTEMARKLE, PRESIDENT, STUDENT NURSES' ASSOCIATION, UNDERGRADUATE STUDENT, GEORGE MASON UNIVERSITY

Ms. CLIFFORD. Yes, thank you, Senator. I will be happy to do that. In fact, actually, I plan to only highlight my testimony. Also to put everyone at ease, I will be the only one presenting testimony. The others with me are here to answer questions as necessary.

Doris Blaney, Dr. Blaney is a member of the ANA Commission on Nursing Education and professor and chairperson, Division of Nursing, Indiana University Northwest, Gary, Ind.

Dean Linda Amos is here representing the American Association of Colleges of Nursing. She is dean and professor, School of Nursing, Boston University, Boston, Mass.

Dean Anna Coles is representing the National League for Nursing. She is dean, College of Nursing, Howard University, Washington, D.C.

Ms. Connie Brotemarkle is president, Student Nurses' Association of Virginia, undergraduate student at George Mason University, Fairfax, Va.

Senator SCHWEIKER. Let me just say that we appreciate your being out of order at this point and your understanding that, and I would not have agreed to that if there was some controversy before us in terms of this committee's view on your position.

We do appreciate your being last and going out of order, and if it had adversely affected you, why we would not have done it.

Ms. CLIFFORD. We understand why we are last and also the committee's favorable view on our position.

I am Joyce Clifford, speaking on behalf of the American Nurses' Association. As director of nursing services at Boston's Beth Israel Hospital, I am also speaking as a concerned nurse administrator and a troubled employer of registered professional nurses.

My experience spans nearly 23 years in the practice of nursing in Connecticut, New Hampshire, Alabama, Indiana, and Massachusetts. For more than half of this time I have been involved in nursing administration.

Typically, the most overriding issue that I have had to face is the proper staffing of health care programs to meet the requirements of patients and their families at a time when they most critically need assistance.

Throughout my lifetime in nursing, there has been and continues to be a shortage of well-prepared nurses to meet these requirements.

President Carter's conclusion, and I quote, that "the outlook is good for adequate sustained growth in the supply of nurses," end of quote, runs contrary to the conclusions arrived at by those of us involved in the field.

Nursing service administrators throughout this country report high vacancy rates in R.N. positions. A recent survey of the American Hospital Association revealed that of 43 State hospital associations contacted, 33 reported an overall shortage of nurses.

I have some other statistics that I will not repeat at this point. They are in my prepared text.

I am troubled by these facts. There is a shortage of nurses in this country and discontinuation of funds for the preparation of nurses will go right to the bedside of the consumer. Their health care needs will be placed at risk as the resources decline for training to meet these needs. We are all too aware of the dissatisfaction expressed by the consumer of fragmented health care. We have heard the cry for continuity and improved planning for high quality care. We have begun to make changes in the delivery system but without support for the continued preparation of well-qualified nurses; we will not be able to continue with this.

But it is more than numbers. It is more than the high vacancy rates in registered nurse positions throughout this country. Continuation of these funds is critical for specialized areas and the development of leadership positions.

The intensity and complexity of patient care shows no sign of slowing down. Such complexity has a direct impact on the utilization of nurses, the need for not just more but for more skillfully prepared professionals as well.

As we know, the average length of a patient's hospital stay continues to be shortened. At the same time, the complexity of care required by the shortened time frame has increased substantially.

The level of complexity I am speaking of did not exist in the past. Patients died before they arrived at this level of complexity. We boast of the most advanced technology and the most sophisticated medical regimens.

When confronted with serious illness, all of us demand and expect to receive the desired outcomes of this level of knowledge. Survival alone is no longer good enough. The quality of life is of ultimate importance.

Hospitals and other health care agencies have responded to the challenge of technological complexity intermingled with requirements to be more personal and humane in our approach to the patient.

One of the most significant of these developments is primary nursing where the registered nurse assumes full 24-hour accountability for the nursing plan of care for her specific patients.

Primary nursing means that finally the registered nurse is providing care directly to a caseload of patients rather than care through others. It means that coordination of diagnoses, therapy and education with patients, family members, physicians, and other health care personnel is the responsibility of the registered professional nurse.

Such coordination is crucial in today's complex system, and it demands highly trained, well-prepared professionals who respond to more than the increased technical and medical specialization.

It demands professionals who are prepared to confront complex ethical decisions, the serious issues of informed consent, patient's rights and the patient's ability to cope following discharge.

A major objective of the Nurse Training Act was to prepare nurses at the graduate level to fill leadership positions in nursing service, administration and supervision.

While numbers of nurses is of significance to us, it is in this area, the need for well qualified nurse leaders and managers that you will find the deepest consensus and concern among nursing service administrators.

Even in Boston, with its relatively high ratio of nurses, we face serious hurdles as we attempt to fill leadership positions. At the Beth Israel hospital, for example, an open head nurse position, our most critical first line manager averages 4 to 6 months to fill with the right person.

Even then we find ourselves providing extensive on-the-job training and continuing education in order to prepare the nurse manager for that role. The average yearly budget responsibility of a head nurse at the Beth Israel Hospital ranges from \$300,000 to over \$500,000.

Our head nurses assume complete managerial accountability for all staff assigned to their unit, staff they have interviewed and selected themselves. Such head nurses directly influence the efficiency and effectiveness of the delivery system. They manage an average of 30 staff members, a major responsibility in any organization.

Equally as critical is the dearth of qualified nursing service administrators in this country. Results provided by 5,326 hospitals in a 1977 survey conducted by the American Society of Nursing Service Administrators shows that only 27.3 percent of the nurse administrators in these hospitals held a masters degree.

Nearly half or 48.1 percent of the nursing service administrators do not hold even a baccalaureate degree. Yet nursing service administrators in this country assume accountability for 40 to 60 percent of the hospital's budget and for one-third to one-half of its personnel.

We cannot afford to have unprepared people with such responsibilities. Continued support for the preparation of nurse managers and nurse administrators is thus appropriate not only for adequate numbers of nurses, not only for adequate preparation of such nurses, but also to help make the product, patient care, both effective and prudent in cost.

We appreciate the way this committee has responded to this bill and urge prompt enactment of the Nurse Training Act S.230 in



order that the nursing resources of the future will not be further jeopardized. Thank you.

Senator SCHWEIKER. Thank you. One of the real issues, and you have touched on it obviously right off in your statement, is whether there is a shortage or not, and I would just like to spend a minute or two going back, because there seems to be a strong difference of opinion here with the Carter administration saying that we have enough; there is no shortage; and therefore, kill the whole program.

You say a survey of the American Hospital Association revealed that of 43 State hospital associations contacted 33 reported an overall shortage of nurses.

Ms. CLIFFORD. That is correct.

Senator SCHWEIKER. How does this jibe with what the administration is telling us?

Ms. CLIFFORD. I am unable to answer that, Senator, other than the fact that these figures come from those of us in the field. These are figures provided from current budgeted vacancies—I can tell you my vacancy rate right now. Earlier Senator Kennedy spoke of Mass General Hospital with 150 vacancies in nursing. Boston City Hospital, the same. And throughout the country there are similar kinds of statistics reported by directors of nursing in terms of budgeted positions that are vacant.

Senator SCHWEIKER. California 17 percent unfilled; Arizona 21 percent. Milwaukee 12 percent.

Ms. CLIFFORD. Yes, sir.

Senator SCHWEIKER. How do we get the nurses into the geographic areas and the hospitals that we need them, Ms. Clifford? In other words, how do we get them where we need them. Assuming that we give you resources now to do the job which obviously is at issue very deeply, but assuming we do that, how do we get them where we need them?

Ms. CLIFFORD. I think that as delivery systems for nursing care for example within hospitals change, and they will change if we have increased resources, we will then be able to attract well prepared nurses into geographic areas that have been in the past unable to attract them.

I would also like to comment, however, that in terms of distribution we need to look at it from a comprehensive viewpoint. It is not only a national geographical issue. But even within, for instance, a State such as Massachusetts, which I am most familiar with, you must look in terms of geographical distribution within the State.

A high ratio of nurses may exist, but there continues to be a dearth of nurses in different parts of the State and also within hospitals themselves. For example, many of the vacancies I have cited are on the—what we call the off shifts, evening and nights, weekends. There is much difficulty within cities, inner cities, and also some rural areas, to get nurses to fill these off-shift positions.

Senator SCHWEIKER. One of the problems, as you well know is the early dropout rate. Would you comment on that as to what we might do to keep nurses in the nursing force?

Ms. CLIFFORD. I am a little confused. Are you speaking of the early dropout rate in schools?



Senator SCHWEIKER. Economists have given us figures that there is a dropout rate of 30 to 40 percent of people, of nurses in the work force, and some of them are as simple as getting married, you know, and others are going on to other occupations, changing jobs.

Obviously, this causes shortages, and this maybe accounts for the difference between our figures and the administrations figures.

Ms. CLIFFORD. It is quite probable that there are some discrepancies between our statistics related to the number of licensed professional nurses and the number of active nurses willing to work.

We are a female profession predominantly, and we are still subject to many of those circumstances related to female professions, marriage and children continuing to be major reasons for such attrition.

Also, more currently there are other career opportunities opening up for women that are at a higher pay scale. So salary is one of the things we need to be looking at.

Senator SCHWEIKER. So pay is an important point.

Ms. CLIFFORD. I would also comment that when you look at the intensity of care occurring in all hospitals, not just medical centers such as the one I am in, but even within the community hospital, the syndrome now referred to as burnout is really very evident. We do have to look in terms of how can we make changes within the particular delivery systems which will allow nurses to be able to continue to practice nursing in a satisfied manner.

One of the ways I think we have begun to address this issue is through the development of primary nursing, where we are bringing the nurse back to the bedside, working with a caseload of patients, being able to deliver professional nursing care and to be able to do it herself rather than supervising, at a very expensive cost, by the way, less prepared auxiliary people.

Senator SCHWEIKER. All right. I appreciate your comments very much and your patience as well.

The Senate Health Subcommittee will stand in recess.

[Whereas, at 12:40 p.m., the proceedings were adjourned at the call of the Chair.]

## A P P E N D I X

The following testimony was submitted for the record:

I. S. 544, ''The Health Planning Amendments of 1979''

II. S. 230, ''The Nurse Training Act''

III. S. 590, ''The Clinical Laboratory Improvement Act of 1979''

## I. S. 544, "The Health Planning Amendments of 1979"



1747 Pennsylvania Ave., N.W., Suite 600, Washington, D.C. 20006

March 25, 1979

Committee on Labor and Human Resources  
 Subcommittee on Health and Scientific Research  
 309 D Senate Courts Building  
 First and C Streets, N.E.  
 Washington, D.C. 20510

Please find enclosed five copies of the "Statement of the American Clinical Laboratory Association on S. 544 - The Health Planning Amendments of 1979" for inclusion in the record of the Committee's hearings on that bill.

If more copies are needed, or there are any questions about this statement, please contact me at the address listed above.

Thank you for your assistance.

Sincerely,

Hope S. Foster

Enclosures

General Counsel:

H. Robert Halper, Esq.  
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 1747 Pennsylvania Ave., N.W.  
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STATEMENT OF THE AMERICAN  
CLINICAL LABORATORY ASSOCIATION  
ON S. 544 -  
THE HEALTH PLANNING AMENDMENTS OF 1979  
MARCH, 1979

The American Clinical Laboratory Association, an organization of independent, federally regulated, proprietary clinical laboratories, submits this statement to urge the Committee on Labor and Human Resources to amend § 141 of S. 544 to exempt the purchases of diagnostic equipment by independent clinical laboratories from the definition of institutional health services. ACLA recognizes that §136 would only apply the prior approval requirements of certificate of need to purchases of such equipment that "will be used to provide services on a regular basis for inpatients of a hospital." However, as §136 currently reads, many independent laboratories could be subject to certificate of need requirements, as such laboratories could be deemed to be regularly providing services to inpatients, based on the reference work they may do for hospitals even though the total amount of such reference testing is very slight when compared with the total number of tests provided by these laboratories. Independent laboratories are not appropriately subject to certificate of need requirements for the following reasons:

1) Independent laboratories are one of the few components of the health care industry that operate in competition. ACLA has demonstrated the existence and effects of this competition in the STATEMENT ON COMPETITION IN THE INDEPENDENT LABORATORY MARKET which ACLA submitted to the Subcommittee on Health and Scientific Research last year. This competition regulates major medical equipment purchases more effectively and efficiently than a planning agency could.

2) Independent laboratories are charge-reimbursed while hospitals are cost-reimbursed. Since independent laboratories are charge reimbursed, not cost reimbursed, they bear the risk of unwise diagnostic equipment purchases. No third party carrier picks up the costs incurred by independent laboratories. Therefore, review of the costs they assume is not necessary. These labs cannot pass on the costs of unwise investments as their prices are set in a competitive market and they are charge reimbursed.

(3) Adoption of an amendment exempting independent laboratories from prior approval requirements will not adversely affect quality since the exemption would only apply to Medicare Certified Laboratories.

(4) Expanding the jurisdiction of health planning agencies to include independent laboratories will overburden the already heavily committed planning agencies.

(5) Leaving independent laboratories out of the planning program will not effect the utilization of testing services since control of utilization is in the hands of physicians, third party carriers and PSROs, not laboratories. Imposing planning requirements on laboratories is therefore not the appropriate vehicle to solve the overutilization problem.

(6) Requiring independent laboratories to disclose their purchase plans prior to acquisition will destroy the competitive edge of surprise and will deleteriously effect the competitive marketplace in which these laboratories operate.

The amendment that ACLA seeks to exempt independent laboratories would strike the period at line 23 of page 36 and insert in lieu thereof a comma and the following:

except such equipment utilized exclusively to perform diagnostic laboratory services in a clinical laboratory which is independent of a physician's office and a hospital and which has been determined under title XVIII of the Social Security Act as meeting the requirements of paragraphs (10) and (11) of section 1861(s) of such Act.

Thus, if this amendment were adopted the definition of diagnostic and therapeutic equipment purchases subject to certificate of need requirements would read

§ 1531(5)

The term "institutional health services" means...(ii) diagnostic or therapeutic equipment, acquired through purchase, rental, lease, or gift, valued at the time of acquisition in excess of \$150,000, used in the delivery of health care services by a health care facility except such equipment utilized exclusively to perform diagnostic laboratory services in a clinical laboratory which is independent of a physician's office and a hospital and which has been determined under Title XVIII of the Social Security Act as meeting the requirements of paragraphs (10) and (11) of section 1861(s) of such Act.

ACLA submits that adoption of this amendment will preserve the benefits that have accrued to the system from the competition exerted by the independent laboratory and will in no way undermine the goals of the planning program.<sup>1/</sup> However, should the Committee on Labor and Human Resources determine that it cannot exempt independent laboratories from §141, it should consider amendment to §136 to strike the words "on a regular basis" at lines 22 and 23 of page 33 and add the words "primarily" between "used" and "to" at line 22 of page 33. If this amendment were adopted, section 1523(d)(1)(B) would read as follows:

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<sup>1/</sup> For a detailed discussion of these benefits and the fact that an exemption will not injure the planning system, see "Statement of the American Clinical Laboratory Association on S. 2410, The Health Planning Amendments of 1978 (February 22, 1978)", submitted by ACLA on S. 544's predecessor.

The State Agency finds, within thirty days after the date it receives a notice in accordance with paragraph (2) with respect to such acquisition, that the equipment will be used primarily to provide services ~~on a regular basis~~ for inpatients of a hospital.

This amendment will assure that an independent laboratory which purchases a piece of equipment that will be used minimally but regularly to provide reference testing to hospitals and which will be primarily used to provide testing services to others than inpatients will not be subjected to the expensive, time-consuming and competition lessening process of certificate of need.

ACLA will be happy to provide additional information or answer questions at the Committee's pleasure.

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## AMERICAN DENTAL ASSOCIATION

WASHINGTON OFFICE • SUITE 1004 / 1101—17TH STREET, N.W. • WASHINGTON, D.C. 20036 • PHONE 202/833-3036

March 30, 1979

The Honorable Edward M. Kennedy  
Chairman  
Subcommittee on Health and Scientific  
Research  
Committee on Human Resources  
4230 Dirksen Senate Office Building  
Washington, D. C. 20510

Dear Senator Kennedy:

I am writing on behalf of the American Dental Association to express our views on S. 544, the Health Planning Amendments of 1979, S. 590, the Clinical Laboratory Improvements Act and certain other items which are before your Subcommittee. I request that this letter be made a part of the record of hearings held by your Subcommittee on these bills.

Health Planning Amendments

Since enactment of the National Health Planning and Resources Development Act the American Dental Association has attempted to participate to the fullest extent possible in its development and implementation. We continue this effort despite the restrictiveness of P.L. 93-641 with regard to representation of and participation by dentists in this program.

The ADA believes strongly that health planning should be open and that every group in the community with expert knowledge and deep interest should be welcomed within the process. Unfortunately this presently is not the case. Currently the various categories of health professionals and allied health personnel must compete for membership on the Health Systems Agencies, the Statewide Health Coordinating Council, and the National Planning Council. Certainly the dentists of each community can offer worthwhile assistance with respect to a segment of the health care delivery system that on a national annual basis involves over 100 million patients and \$10 billion in expenditures.



The Honorable Edward M. Kennedy

Page 2

March 30, 1979

We note that Section 101(a) of S. 544 would expand the membership of the National Council from 15 to 20 members with a stipulation that at least 8 of these members be consumers. The ADA believes that in addition to this requirement, S. 544 also should include a requirement for representation of at least one practicing dentist on the Council.

Section 113 of the bill would broaden the definition of health care provider to include "non-professional health workers" and "other providers of health and mental health care." The ADA believes it is essential that practicing dentists also have a voice at the local and state planning levels and strongly urges that Section 113 include language to accomplish this objective. A guarantee in the law that practicing dentists will have a voice at the local, state, and national levels is necessary. We strongly urge that the above amendments be adopted.

Section 105(c) would require the assignment of at least one Health Systems Agency staff member to provide assistance to consumer members of HSA governing bodies. We support this concept noting that it is most important that all governing body members have a minimal level of knowledge and information on which to base their judgments. However we would caution that all HSA members, not just consumers, will have special needs at one time or another for information and assistance. The needs of these members must not be neglected.

We have expressed in the past our deep concern over unjustified Federal intervention in local health planning activities. We have opposed and still oppose placing unduly broad discretionary powers in the hands of the Secretary of Health, Education, and Welfare permitting him to override or bypass local and state health planning agencies and units of government.

Federal legislation should have the flexibility to allow local jurisdictions to respond to their own unique problems. We are pleased with the provisions in Section 119 which would seem to permit this flexibility in local jurisdictions. While we think it is appropriate and necessary that HSAs justify any inconsistencies between their health systems and annual implementation plans and the national guidelines, we would hope that the legislation would make clear that the required "detailed statement" not be burdensome for the local HSAs.

There has been considerable discussion over the need for and extent of possible expansion of certificate of need requirements. The provisions of S. 544 with regard to certificate of need review for equipment purchases are an improvement over the provisions considered in the 95th Congress. While the Association continues to oppose general provisions which would subject private dental offices to certificate of need requirements, there is logic to subjecting purchases of major medical equipment which is to be used in the diagnosis or treatment of hospital

The Honorable Edward M. Kennedy  
 Page 3  
 March 30, 1979

inpatients to certificate of need. A provision such as that in S. 544 addresses what is perhaps a current gap in the planning law.

We would point out however that if "the value of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment" are indeed included in the \$150,000 standard for determining whether equipment is subject to certificate of need (as is stated in S. 544) it is conceivable that the purchase of relatively inexpensive pieces of equipment will then be subject to HSA approval. While expenditures may be necessary for these various preliminary activities, we believe that the thrust of this legislation should be to the equipment itself and that the \$150,000 threshold should apply strictly to the cost of the actual equipment being purchased.

We also are in support of a modification in requirements for the development of Health Systems Plans. In order to allow HSAs to implement their plans before revisions are required, such revisions should be every three years rather than annually as at present.

#### Clinical Laboratory Act

The Clinical Laboratory Improvement Act would substantially revise federal laws pertaining to the regulation of clinical laboratories to establish a system of national standards which must be complied with by laboratories and a requirement that all laboratories be subject to inspection by the HEW Secretary. In addition, the bill would provide that intrastate as well as interstate clinical laboratories be subject to its provisions.

Before making some specific comments with regard to provisions of this bill, I would like to point out our concern with the broad scope of this legislation. Not only is the proposal increasing the number of facilities which will be subject to federal law, it is significantly expanding the role of the federal government with regard to these facilities. We suspect that the burdens which would be imposed on the Department of HEW as well as on those clinical laboratories which would have to comply with the provisions of the bill may outweigh any benefits which could be derived from this legislation. Current law establishes minimum standards which must be met by clinical laboratories. We suggest that necessary improvements be made in existing law along with adequate financial support to implement this law properly. We question whether the extensive revisions proposed in S. 590 are necessary.

The Honorable Edward M. Kennedy  
Page 4  
March 30, 1979

With regard to specific provisions of the bill, we have some concerns with the definition of a laboratory as set out in the bill. We are concerned with the scope of these provisions which include facilities for the collection, processing, and transmission of specified materials. Without a further clarification as to the type of facility contemplated, we believe that the definition could include individual dental offices, even if no laboratory exists in the office, in that dentists can provide for the collection and transmission of such materials. We recommend that there be a clarification of the purposes of this part of the definition and that the language be made specific as it relates to these purposes in order to assure that individual offices are not included within the scope of this definition.

The bill authorizes the Secretary to provide exemptions from the national standards requirements for clinical laboratories located in the offices of and operated by licensed physicians, dentists, podiatrists, or groups of such practitioners. This exemption is authorized when the tests or procedures performed in such laboratories are performed by the practitioner in connection with the treatment of his patients. Exemptions also are authorized for laboratories located in the office of a licensed physician, dentist, podiatrist, or a group of not more than five such practitioners, when the procedures are performed by laboratory personnel other than the practitioner. In order to be eligible for this exemption, applicants would have to provide detailed information concerning the qualifications of personnel who participate in the conduct of tests and procedures, a specification of the types of tests and procedures conducted, the type of proficiency testing participated in by such personnel, and a description of the quality control programs in effect in the laboratory for which the application is submitted. In addition, the bill would exempt from compliance with the national standards any laboratory which participates in an approved proficiency testing program.

As we have mentioned previously, the standards proposed by this bill are extensive and could provide an extreme burden on individual dentists and other health care providers who would be required to comply with them. The provisions in the bill authorizing exemptions seem to us to be quite vague. First the bill would allow the granting of an exemption to a laboratory in which the physician, dentist, or podiatrist performs the services of the laboratory. It would appear to us that this possible exemption relates to a situation which in practicality does not exist, i.e. the provider himself performing the laboratory tests.

In addition exemptions would be allowed for laboratories located in a practitioner's office when the laboratory procedures are performed by laboratory personnel if the practice includes no more than five such practitioners. The benefits of an office based laboratory are considerable.

The Honorable Edward M. Kennedy  
Page 5  
March 30, 1979

Such laboratories can increase provider efficiency, reduce costs, and add to patient convenience. These benefits would occur regardless of whether the practitioner or his personnel perform the test and regardless of whether the patient is being treated by a practitioner in a small or large group. The limitation of this possible exemption to groups of five providers or less is not appropriate and should be deleted.

The discretionary authority given to the Secretary to provide exemptions for office based laboratories can be implemented only after the Secretary is supplied with certain information relating to the qualifications and activities of laboratory personnel. There is no indication in the bill as to whether the information obtained through this procedure is to be taken into account by the Secretary in his decision as to whether or not an exemption will be allowed and, if he is to so consider this material, there is no indication as to what conditions may exist in a laboratory which would enable that laboratory to merit exemption.

We recommend that this legislation be amended to mandate that all laboratories which are located within the offices of individual, or groups of, dentists, physicians, or podiatrists be exempt from the requirements of this bill so long as the activities undertaken within that laboratory are for the patients of the providers involved. Although there may be some benefit in obtaining the type of information outlined in this section with regard to laboratory personnel, we are concerned that the extent of information required could seriously hinder the willingness and ability of individual providers to continue to operate beneficial laboratories. We urge that any such information which may be required be as limited as possible.

#### Other Legislation

I also would like to comment on certain provisions of S. 690, the Emergency Medical Services Systems and Health Information and Promotion Extensions of 1979 which was developed by the Administration.

Section 4 of this bill would increase the authorization for project grants for preventive health services under Section 317(j)(4) of the Public Health Service Act. Under this subsection grants can be made for preventive health services programs other than those for which specific authorizations are established under the law.

It is under the authority of Section 317(j)(4) that federal funding for fluoridation activities at the community level are authorized. As you know fluoridation of public water supplies at optimal levels is one of

The Honorable Edward M. Kennedy  
Page 6  
March 30, 1979

the most effective disease prevention measures known to science. More than 30 years of experience has demonstrated that water fluoridation is safe and economical and that it can reduce the incidence of dental caries by as much as 65%.

President Carter in his fiscal year 1980 budget has requested that \$6.2 million be made available for fluoridation activities. This funding would be provided through subsection 317(j)(4). However, currently the authorization limit under that subsection is \$1 million for fiscal year 1980. Section 4 of S. 690 would increase this authorization level to \$5 million for fiscal year 1980 and the sums necessary for fiscal years 1981 and 1982. The dental profession strongly urges your Subcommittee to adopt this increased authorization level for support of a preventive health activity which has been shown to save over \$30 in health care expenses for each dollar expended.

Section 6 of S. 690 would delete a current requirement under the Health Professions Educational Assistance Act that at least 10% of amounts appropriated for residencies in family medicine and the general practice of dentistry be for general dentistry. While the dental profession has maintained a very acceptable balance between general dentistry and specialization the support which can be provided through this authority of the health manpower law for general dentistry residencies can have a major impact on future directions of dental residency training.

The requirement that a specific percentage of funds appropriated for the general residency program be for dental residencies was added as part of the 1976 amendments to the health manpower laws. The Administration does not challenge the appropriateness of this relatively new provision but recommends its deletion simply on the premise that this will reduce federal spending. The Congressional decision to assure a certain allocation of funds for general dentistry residency programs was and is a sound one. The Administration's proposal to delete this requirement should be rejected.

Thank you for your consideration of the Association's views with regard to these matters.

Sincerely,

*Wm E Allen*

William E. Allen, D.D.S.  
Chairman  
Council on Legislation

NATIONAL HEALTH PLANNING AND RESOURCES DEVELOPMENT ACT  
OF 1974

Amendment Proposals

March, 1979

AMERICAN HOSPITAL ASSOCIATION

The following outlines the policy positions regarding the American Hospital Association amendments to the National Health Planning and Resources Development Act of 1974. These amendments reflect hospital concerns for the implementation of this Act and for achieving an orderly planning process for the health care industry.

Each amendment issue is described in the following way: First, there is the policy position of the American Hospital Association. Second, the rationale supporting each amendment is shown. Third, in most cases the new statutory language is presented, with new language in italics and deletions crossed through.

## TABLE OF CONTENTS

I.	Clarification of the Relationship between National Guidelines and Local Planning	1
II.	Coverage of Certificate of Need	3
III.	Institutional Representation on Planning Agencies, Boards and Councils	7
IV.	Due Process Requirements for Reviews	11
	1. Notice of Reviews	12
	2. Comparative Hearings ("Batch Processing")	12
	3. HSA Hearings	12
	4. SHPDA Hearings	13
	5. Opportunity to Appear	13
	6. Cross-examination	13
	7. Elimination of the "Pocket Veto"	14
	8. Administrative Appeal	14
	9. Judicial Review	15
V.	Appropriateness Review	20
VI.	Coordination between HSAs and Health Care Institutions	25
VII.	Penalties for States Not in Compliance	27
VIII.	Provision of Free Care	29
IX.	Uniform Cost Accounting and Reporting Systems	31
X.	Federal Hospital Construction Requirements	32
XI.	Redefine Indirect Providers	36
XII.	Review Functions of Health Systems Agencies and Statewide Health Coordinating Councils	38
XIII.	Planning Grants for Health Systems Agencies	41
XIV.	Private Contributions to Health Systems Agencies	43
XV.	Prohibition Against Purchasers of Health Care Being Designated as Health Systems Agency	45
XVI.	Transfer of Health Services Development Grants Functions to State Agencies	47

I. Clarification of the Relationship between National Guidelines and Local Planning

A. Policy Position

The American Hospital Association supports amendment of P.L. 93-641 to make it clear that planning activities are to be conducted primarily at the local level, with a minimum of interference from statewide and federal agencies.

B. Rationale

In the preamble to proposed National Health Planning Guidelines issued September 23, 1977, the Department of Health, Education and Welfare asserted its view that the national guidelines specified by Section 1501 of P.L. 93-641 were required to be included as minimum goals and standards in local health systems plans (HSPs), annual implementation plans (AIPs) and statewide health plans as well as in state medical facilities plans. This was an effort to impose "top down" planning instead of "bottom up" planning which we believe was clearly intended by Congress in passing the statute. Mandatory guidelines are a contradiction in terms which would hamstring health systems agencies in their planning efforts and would give preeminence to the role of federal planning. Such a result is contrary to the express requirement of the statute that health planning must be "responsive to the unique needs and resources of the [health service] area." [Section 1513(b)(2)(B).]

To reinforce the balance between local and national authority which was struck by the original enactment, AHA proposes an amendment which will make it clear that although the national guidelines must be taken into consideration by HSAs, they are not to be considered as inflexible, mandatory parts of the local planning process.

C. Legislative Language

During the 95th Congress, House Bill 11488, as reported, and Senate Bill 2410, as passed, both contained an amendment to remove the statutory requirement that areawide and state plans be "consistent with" the national guidelines. The language of the House Bill is set forth below.

FUNCTIONS OF HEALTH SYSTEMS AGENCIES  
Section 1513(b)(2)

"(C) which take into account ~~and-is-consistent-with~~ the national guidelines for health planning policy issued by the Secretary under Section 1501 respecting supply, distribution, and organization of health resources and services.



I. Clarification of the Relationship between National Guidelines and Local Planning (cont'd)

*(5) The Agency shall make its HSP available to the State health planning and development agency of each state in which the health service area of the health systems agency is located for inclusion in the preliminary State health plan to be prepared under Section 1523(a)(2) and, if the goals contained in the HSP are not consistent with guidelines issued by the Secretary under Section 1501, it shall provide the State Agency with a detailed statement of the reasons for the inconsistency between such goals and guidelines. When making such HSP available to the Statewide Health Coordinating Council under Section 1524(c)(2)(A), the agency shall also report such statement to such Council."*

## II. Coverage of Certificate of Need

### A. Policy Position

The American Hospital Association supports an amendment to modify mandatory coverage of state certificate of need laws by (i) including all comparable facilities, expenditures and services regardless of ownership or location, (ii) eliminating coverage of predevelopment activities, and (iii) clarifying the definition of new institutional health services.

### B. Rationale

(1) Major Medical Equipment Coverage. The facilities and programs subject to review by health systems agencies and approved by state certificate of need (CON) agencies should include all comparable facilities and services irrespective of ownership or location. Only through coverage of all comparable services and equipment, without arbitrary exemptions, can the goals of the legislation for comprehensive health planning be realized.

Of particular import is the extension of mandatory coverage of state CON legislation to major medical equipment purchased by physicians or other non-institutional providers. Without such comprehensive coverage, responsible institutions are concerned that their efforts to develop programs of shared services for this technology would be thwarted by uncontrolled competition from their own medical staffs as well as from physicians affiliated with other hospitals or those without staff appointments in the immediate service area. Unregulated competitors could divert utilization from approved projects and equipment pushing regulated competitors below the economic breakeven point.

A provision mandating inclusion of such equipment in CON legislation was passed by the Senate during the 95th Congress and similar legislative language is suggested below.

(2) Predevelopment Activities. It is clearly in the public interest for hospitals and other health care institutions to plan cautiously and methodically for the development of any expansion of their services and facilities, exploring in some detail all possible alternative sources and uses of funds and resources. Such exploration can be expensive, although few would deny its cost effectiveness. Often, sound concern for the future, including cost containment concerns, virtually requires purchase of adjacent properties, whenever they come on the market, even though no specific use has been determined for them. These activities should not be subject to CON requirements because of the delay and notoriety involved, which could frustrate their purposes.

## II. Coverage of Certificate of Need (cont'd)

Exercising the option available under Section 1523(a)(4)(A), several states have elected to require prior approval of predevelopment activities, including site acquisitions, architectural studies, market research and feasibility reports. This requirement often adds an extra, expensive step to the CON process--in effect, a permit to apply for a permit. It also tends to stultify innovation by institutions, since all information and ideas become public property when submitted to the HSA.

(3) Replacement and Modernization. A substantial proportion of capital expenditures by hospitals is made to replace existing facilities and equipment because of depreciation or obsolescence. Obviously, in making such a purchase, the most improved version of such equipment should usually be purchased in order to obtain highest value. In some instances, state or area agencies have insisted on reviewing even expenditures of less than the statistical CON threshold because the latest model of the equipment will perform more functions than the old one being replaced. The justification is that the additional functions constitute a "new service." Again, such an interpretation of the statutory language is expensive to both institutions and agencies and tends to hinder efforts to improve the quality and, often, the cost effectiveness of health care services. An amendment is suggested to correct this problem.

### C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act in accord with the above policy:

#### STATE HEALTH PLANNING AND DEVELOPMENT FUNCTIONS

"SEC. 1523. (a) Each State Agency of a State designated under section 1521(b)(3) shall, except as authorized under subsection (b), perform within the State the following functions:

\* \* \*

"(4)(A) Serve as the designated planning agency of the State for the purposes of section 1122 of the Social Security Act if the State has made an agreement pursuant to such section, and (B) administer a State certificate of need program which

## II. Coverage of Certificate of Need (cont'd)

a pplies to new institutional health services proposed to be offered or developed within the State and which is satisfactory to the Secretary. Such program shall provide for review and determination of need prior to the time such services, facilities, and organizations are offered or developed ~~ex-substantial expenditures-are-undertaken-in-preparation-for-such-offering~~ ~~ex-developement~~, and provide that only those services, facilities, and organizations found to be needed shall be offered or developed in the State. In performing its functions under this paragraph the State Agency shall consider recommendations made by health systems agencies under section 1513(f)."

\* \* \*

"(c) The State Program shall not include any provision for the review of expenditures by or on behalf of a health care facility or health maintenance organization made in preparation for the offering or development of a new institutional health service or any arrangement or commitment made for financing the offering or development of the new institutional health service."

## DEFINITIONS

## Section 1531

\* \* \*

"(5) (A) The term 'institutional health services' means (i) the health services provided by or through health care facilities and health maintenance organizations ~~(as-such-facilities-and organizations-are-defined-in-regulations-prescribed-under-section 1122-of-the-Social-Security-Act)-and-includes-the-entities~~ through-which-such-services-are-provided, as defined in regulations of the Secretary, irrespective of ownership or location, if such services entail annual operating costs of \$150,000 or more; and (ii) diagnostic or therapeutic equipment, irrespective of ownership or location, acquired through purchase, rental, lease, or gift, valued at the time of acquisition in excess of \$150,000, used in the delivery of health care services by any person, institution, or other entity.

"(B) In determining whether diagnostic or therapeutic equipment has a value in excess of \$150,000 for purposes of subparagraph (A), the value of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment shall be included.

## II. Coverage of Certificate of Need (cont'd)

*(C) An institutional health service shall not be deemed to be "new" if it represents only a technological or scientific improvement of an institutional health service already being offered by the same person, facility or organization."*

### III. Institutional Representation on Planning Agencies, Boards and Councils

#### A. Policy Position

The American Hospital Association supports amendments to ensure hospital representation on planning agency boards and councils at all levels and to increase the proportion of direct providers of health care involved in the planning process.

#### B. Rationale

Useful health care planning requires cooperation among all affected components of the community, including consumers, government, physicians, institutions, and other providers. Hospitals are a particularly complex component of the health care system, in which many apparently diverse interests must be reconciled. Hospital administrators must consider the needs and interests of the institution's medical staff, its nurses, its technicians and other practitioners, its non-professional employees and, above all, its patients. Consequently, the hospital administrator's knowledge and experience is invaluable at all levels of planning--local, state and federal--and the expanded use of this expertise in the planning process would improve the acceptability of planning and review decisions.

The principal impact of the statute is upon providers of major institutional services--for the most part, upon hospitals. However, as it is now written, there is no provision to ensure any representation of hospital administration at all levels of the planning structure. An agency board devoid of such representation might fail to consider important issues in discharging its planning and review functions, with the risk of turning the entire process into a confrontation between adversaries, instead of a cooperative effort to solve community problems. Consequently, provisions must be included in the act to provide specifically for the participation of hospital representatives.

AHA's proposed legislation provides that on the local level at least one-half of the providers shall be direct providers and that at least one of them shall be a representative of hospital administration. On the state level, the proposed amendment would increase the proportion of direct providers of health care on the Statewide Health Coordinating Council (SHCC) from one-third to one-half of all provider representatives. The proposed amendment would also serve to ensure that at least one of the provider representatives shall be a representative of hospital administration.

### III. Institutional Representation on Planning Agencies, Boards and Councils (cont'd)

On the national level, the proposed amendment would result in an increase in the number of members on the National Council. The need for the increase results from the inclusion of the Assistant Secretary for Rural Development of the Department of Agriculture as an ex officio member and the addition of two consumer members, including members of urban and rural medically underserved populations; both provisions were included in Senate Bill 2410 during the 95th Congress. In order to provide for a proper balance between consumers and providers, our proposed amendment also provides for an increase in the number of provider members on the Council.

The specific inclusion of a hospital representative on the National Council is a concept which has been supported by the Senate during debate and which must be ensured by specific provision in the Planning Act. The other objectives of the policies stated above were supported by amendments included in HR 11488.

#### C. Legislative Language

The following legislative language would accomplish the policy objectives set forth above, by modifying some features of both bills which were introduced in the 95th Congress.

#### COMPOSITION OF NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

##### Section 1503(b)(1)

"(b)(1) The Council shall be composed of ~~fifteen~~ *not less than eighteen and not more than twenty members*. The Chief Medical Director of the Veterans' Administration, the Assistant Secretary for Health and Environment of the Department of Defense, *the Assistant Secretary for Rural Development of the Department of Agriculture*, and the Assistant Secretary for Health of the Department of Health, Education and Welfare shall be non-voting ex officio members of the Council. The remaining members shall be persons who, as a result of their training, experience, or attainments, are exceptionally well qualified to assist in carrying out the functions of the Council. Of the voting members, not less than ~~five~~ *seven* shall be persons who are not providers of health services *including individuals who are members of urban and rural medically underserved populations; not less than seven shall be persons who are representatives of each*

### III. Institutional Representation on Planning Agencies, Boards and Councils (cont'd)

*of the classifications of providers enumerated in section 1512(b)(3)(C)(ii) at least one of whom shall be a person engaged in the administration of a hospital, not more than three shall be officers or employees of the Federal Government, not less than three shall be members of governing bodies of health systems agencies designated under part B, and not less than three shall be members of Statewide Health Coordinating Councils under section 1524. The two major political parties shall have equal representation among voting members on the Council."*

#### COMPOSITION OF STATEWIDE HEALTH COORDINATING COUNCILS

##### Section 1524(b)(1)(C)

*"(C) Not less than one-third one-half of the providers of health care who are members of a SHCC shall be direct providers of health care (as described in section 1531(3). Members of a SECC who are providers of health care shall include at least one representative of each of the classifications of providers enumerated in section 1512(B)(3)(C)(ii) at least one of whom shall be a person engaged in the administration of a hospital."*

#### COMPOSITION OF HSA BOARDS

##### Section 1512(B)(3)(C)(ii)

*"(ii) The remainder of the members shall be residents of or have their principal place of business in, the health service area served by the agency who are providers of health care and who represent (I) physicians (particularly practicing physicians), dentists, nurses, optometrists, and other health professionals, ~~(II)--health-care-institutions-(particularly-hospitals,-long-term-care-facilities,-substance-abuse-treatment-facilities-and health-maintenance-organizations,-(III)--health-care-insurers,~~ ~~(IV)--health-professional-schools-and-(V)-the-allied-health professions.~~ (II) hospitals and other health care institutions (such as facilities for long-term care and health maintenance organizations), (III) if the health service area contains one or more accredited schools of medicine, the dean of at least one such school, (IV) health professional schools (other than schools of medicine if such schools are represented pursuant to subclause (III), (V) the allied health professions, (VI) health care insurers and (VII) other providers of health care as defined in section 1531(3). Not less than one-third one-half of the providers of health care who are members of the governing body or*



III. Institutional Representation on Planning Agencies, Boards  
and Councils (cont'd)

executive committee of a health systems agency shall be direct providers of health care (as described in section 1531(3) and of such direct providers of health care, at least one shall be a person engaged in the administration of a hospital.

#### IV. Due Process Requirements for Reviews

##### A. Policy Position

The American Hospital Association supports amendments to P.L. 93-641 which would ensure providers the protection of due process procedures during the course of all reviews conducted under the Act, especially those which are regulatory or quasi-judicial.

##### B. Rationale

Congress should specifically require procedures which ensure due process of law for providers in the mandatory certificate of need legislation, to protect important legal and economic rights and to provide a sense of orderliness and fairness which is often absent from the present system, both in project review and planning. At a minimum, the following requirements are suggested:

1. Notice to affected persons of the beginning of all reviews;
2. Comparative hearings on competing projects ("batch processing");
3. Public discussion and debate at the HSA level;
4. A formal hearing prior to the SHPDA decision;
5. Opportunity for all affected persons to appear and present evidence and oral or written arguments and to be represented by counsel;
6. Opportunity for parties to cross-examine witnesses on all factual and statistical matters on which a decision might be based;
7. Elimination of the "pocket veto";
8. Provision for an administrative appeal to an independent hearing officer or agency;
9. Judicial review upon appeal by any party directly and substantially adversely affected by the final administrative decision, with the scope of review being at least the same as that under the federal Administrative Procedures Act.

Most of these procedural requirements were contained in either or both of the amendment bills considered in 1978. Although the concepts are present in many other programs, where they have generally been required by the Constitution or by legislation, some are relatively unfamiliar in the health planning context. However, the introduction of power to enforce severe penalties for non-compliance with CON decisions requires that orderly, fair and responsible procedures be followed in arriving at such decisions.

## IV. Due Process Requirements for Reviews (cont'd)

Although all the above due process requirements are generally recognized as minimum standards, their specific application as requirements of state certificate of need programs merits discussion.

1. Notice. The requirement that notice be given of the beginning of any review cycle is quite important. It provides a fixed starting point for the review cycle and an alert to all interested parties who might wish to develop and present positions on specific projects, on "batched" applications, or on areawide appropriateness reviews of specific institutional health services.

2. Batch Processing. Each HSA should be permitted to establish timetables for submission of applications related to specific services offered or to be offered within its area. This will enable the HSA to make comparisons among institutions and to pass upon projects with better information concerning their interrelationships. It is imperative that HSAs be adequately funded and staffed before they undertake this additional responsibility.

3. HSA Hearing. More specific provisions for public hearings for project reviews at state or local levels would allow for significant input by all interested parties into the certificate of need decision process while still providing each applicant with consistent due process procedures. However, in general, there is little advantage in requiring that a hearing be held by an agency after that agency has rendered its decision. To justify the time and expense involved, the hearing should precede the decision, with post-decision activities being conducted on an appellate basis.

Although section 1532(8) of the statute requires public hearings during the course of project reviews and appropriateness reviews, it is vague as to the stage of the proceedings at which such hearings shall take place. There is a requirement for public hearings "for good cause shown" after HSA and State Agency decisions but, again, the timing and location are not specified. We suggest that it would be appropriate to provide for one public forum (not a formal hearing) at the local level, at which all interested persons would have the opportunity to make statements or present evidence with respect to the application or other review. To provide the maximum opportunity for such participation, such a hearing should be well publicized, informal in nature and conducted in the local community. A summary, although not necessarily a verbatim transcript, should be made, which should become part of the record of the total review process, and form part of the basis for the recommendations of the HSA and the decisions of the State Agency.

## IV. Due Process Requirements for Reviews (cont'd)

4. State Agency Hearing. Following the public meeting at the local level, there should be an opportunity for either the applicant or HSA to request a formal hearing to be conducted by the State Agency prior to its decision. At this time, both parties should be permitted to introduce new evidence, and present arguments and discussions which were not previously made at the original public meeting. The decision of the State Agency should then be subject to an administrative appeal or judicial review, or both, in accordance with laws applicable to other agencies.

5. Opportunity to appear and present evidence. The right of a project's sponsor, or an institution whose services are being reviewed to participate in the public HSA meeting described above is beyond doubt. However, some HSAs have refused to allow sponsors to present any evidence at their full Board meetings and have confined sponsors' statements to unreasonably short time allotments, e.g., five or ten minutes to describe a multimillion dollar project affecting many different departments. In the absence of a presentation at the HSA Board level, it is doubtful that all HSA Board members will fully understand the issues they will vote to decide, since not all will have read or comprehended the often voluminous written material presented to them.

Present law permits severe restrictions on a hospital's ability to appear and present its position to the SHPDA. The proposed regulation discusses only the submission of such information as the SHPDA requests and provides only for a hearing upon a showing of good cause.

The right to appear and present evidence is fundamental and should be guaranteed by the statute. The issues involved in institutional health service reviews and the procedures and processes by which they are decided frequently require the assistance of trained legal counsel at the hearings, and this should also be guaranteed by the statute.

6. Opportunity to cross-examine on factual matters. The right to cross-examine witnesses testifying to factual matters has been termed the most essential element of due process, for cross-examination is the best available test of truth and accuracy. Although cross-examination is not essential to test a conclusory expression of support or opposition, it is vital where facts on

## IV. Due Process Requirements for Reviews (cont'd)

which a decision might be based are placed before the decision making body. Whether those alleged facts are contained in documents or are submitted orally, their accuracy should be subject to cross-examination and analysis. This right can be exercised most effectively by trained legal counsel, to which all participants should be entitled.

7. Elimination of "pocket veto." Due process should ensure elimination of the effect of section 123.407(a) (15) of the CON regulations which mandates a "pocket veto" by requiring state laws to provide that "if the state agency does not make a decision regarding a proposed institution of health service within a period of time specified for state agency review, the proposal shall be deemed to have been found not needed." This mandates a startling inconsistency between section 1122 procedures and those required for state CON laws. Thus, a project might be deemed to be approved for federal reimbursement but be deemed to be disapproved under state law. Grave uncertainty would result from this situation.

Serious discredit could be brought to the planning process by continued use of the "pocket veto." It encourages unnecessary delay and secrecy and can substantially handicap both public and provider understanding of the reasons behind agency actions. In the present inflationary environment, every month of delay in reaching decisions on proposed projects adds perceptibly to the cost of such projects. Federal policy should encourage prompt action and openness in the planning process.

Senate Report No. 95-845 accompanying S2410 was highly critical of the "pocket veto" provision of the regulations promulgated attendant to P.L. 93-641 and found it "the very antithesis of due process." Further, the Report said "... any State Agency which holds itself out as capable of administering a State certificate of need program should be competent to review the required application in a timely and efficient manner..." Similarly, House Report 95-1105, accompanying HR 11488, severely criticized the practice known as "pocket veto." The proposed legislation language set forth below in section C would ensure that pocket vetoes could not occur under any circumstances.

8. Administrative Appeal. An administrative appeal should be required of State Agency decisions to the same extent that such appeals are provided by state law from decisions of other state officers, departments and agencies. A state which

## IV. Due Process Requirements for Reviews (cont'd)

has set up the mechanism for such appeals should be required by federal law to use it in this area.

9. Judicial Review. The 1978 Senate Bill specifically required the availability of judicial review of CON decisions. This is very desirable and is strongly supported by AHA. The group who may institute an appeal should be limited to those "directly and substantially adversely affected" by the decision. This would help to keep the whole system from bogging down in court reviews.

However, S2410 severely restricted the scope of review by the court of the agency's decision, requiring that the decision be affirmed "unless it is arbitrary and capricious, or was not made in accordance with applicable law." This is narrower than the review available of decisions of federal agencies under the federal Administrative Procedure Act, or of decisions of the administrative agencies of most states. No reason is given for the elevation of SHPDA decisions to such super status, nor does experience disclose any reason. It is recommended that the scope of judicial review of SHPDA decisions be broadened to be (i) the same as that generally available with respect to other administrative agencies of the state, or (ii) in the alternative, that available with respect to the decisions of federal agencies.

C. Legislative Language.

The following legislative changes are proposed.

## HEARINGS AND PROCEDURES

Sections 1522(b), 1532(a) and 1532(b)

"State Administrative Program

"Section 1522(b). The State Program of a State must --

"(13) ~~provide-that-if-the-State-Agency-makes-a-decision-in-the performance-of-a-function-under-paragraph-(3)-(4)-(5)-or-(6) of-Section-1533(a)-or-under-title-XVI-which-is-inconsistent-with a-recommendation-made-under-Subsection-(f)-(g)-or-(h)-of Section-1513-by-a-health-systems-agency-with-the-State---~~

## IV. Due Process Requirements for Reviews (cont'd)

"(A)--such decision (and the record upon which it was made) shall, upon request of the health systems agency, be reviewed, under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies, by an agency of the State (other than the State health planning and development agency) designated by the Governor, and

"(B)--the decision of the reviewing agency shall for purposes of this title and title XVI be considered the decision of the State health planning and development agency."

PROCEDURES AND CRITERIA FOR REVIEW  
OF HEALTH SYSTEMS

Section 1532

"(a) In conducting reviews pursuant to subsections (e), (f), and (g), (e), (f), (g), and (h) of section 1513 or in conducting any other reviews of proposed or existing health services, each health systems agency shall (except to the extent approved by the Secretary) follow procedures, and apply criteria, developed and published by the agency in accordance with regulations of the Secretary; and in performing its review functions under section 1523, a State Agency shall (except to the extent approved by the Secretary) follow procedures and apply criteria, developed and published by the State Agency in accordance with regulations of the Secretary. Procedures and criteria for reviews by health systems agencies and State Agencies may vary according to the purpose for which a particular review is being conducted or the type of health services being reviewed. Procedures and criteria for reviews by health systems agencies pursuant to section 1513(f) and reviews by State Agencies pursuant to paragraphs (4) and (5) of section 1523(a) must provide that applications be submitted in accordance with timetables established by such agencies; that such reviews be undertaken in a timely fashion; and that completed applications pertaining to similar types of services or facilities affecting the same service area are considered in relation to each other at appropriate times (but no less often than twice a year). Procedures and criteria for reviews by health systems agencies pursuant to section 1513(g) and by State Agencies pursuant to section 1523(a)(6) must provide that reviews of similar types of institutional health services affecting the same service area be considered in relation to each other. Health systems agencies

## IV. Due Process Requirements for Reviews (cont'd)

*and State Agencies within a State shall cooperate in the development of procedures and criteria under this subsection, to the extent appropriate to the achievement of efficiency in their reviews and consistency in criteria for such reviews.*

"(b) Each health systems agency and State Agency shall include in the procedures required by subsection (a) at least the following:

"(1) Written notification to affected persons and to all other persons who have asked to have their names placed on a mailing list maintained by the agency or the State Agency within five days of the date that all information described in paragraph (3) is submitted.

"(2) Schedules for reviews conducted in discharge of the functions described in paragraph (4) of subsection 1523(a) which provide that no such review shall, ~~to the extent practicable~~ except with the consent of the person subject to such review, take longer than ninety days from the date that notification described in paragraph (1) is made. Failure of the State Agency to act on a proposal within such period shall be deemed to constitute approval of such proposal."

"(3) Provision for persons subject to a review to submit to the agency or State Agency (in such form and manner as the agency or State Agency shall prescribe and publish) such information as the agency or State Agency may require concerning the subject of such review.

"(4) Submission of applications (subject to review by a health systems agency or a State Agency) made under this Act or other provisions of law for Federal financial assistance for health services to the health systems agency or State Agency at such time and in such manner as it may require.

"(5) Submission of periodic reports by providers of health services and other persons subject to agency or State Agency review respecting the development of proposals subject to review.

"(6) Provision for written findings which state the basis for any final decision or recommendation made by the agency or State Agency.



## IV. Due Process Requirements for Reviews (cont'd)

"(7) Notification. *Timely notification of providers of health services and other persons subject to agency or State Agency review of the status of the agency or State Agency review of the health service or proposals subject to review, findings made in the course of such review, and other appropriate information respecting such review.*

"(8) Provision for *informal* public hearings in the course of agency review at which members of the public shall have opportunity to make statements and present relevant evidence; ~~or provision for formal hearings to be conducted by the State Agency review prior to its decision, if requested by persons directly affected by the review; the agency or the entity proposing the project or whose services are being reviewed. and provision for for public hearings, for good cause shown, respecting agency and State Agency decisions.~~ Any person who is adversely affected by a final decision of the State Agency pursuant to (4), (5), or (6) of section 1523(a) may, within sixty (60) days appeal such decision to an independent hearing officer or other agency of the State in the manner provided by State law.

"(9) Preparation and publication of regular reports by the agency and State Agency of the reviews being conducted (including a statement concerning the status of each such review) and of the reviews completed by the agency and State Agency (including a general statement of the findings and decisions made in the course of such reviews) since the publication of the last such report.

"(10) Access by the general public to all applications reviewed by the agency and State Agency and to all other written materials pertinent to any agency or State Agency review, *except to personnel records and data regarding an individual employee the disclosure of which would constitute a clearly unwarranted invasion of the personal privacy of such employee.*

"(11) In the case of construction projects, submission to the agency and State Agency by the entities proposing the projects of letters of intent in such details as may be necessary to inform the agency and State Agency of the scope and nature of the projects at the earliest possible opportunity in the course of planning of such construction projects.

## IV. Due Process Requirements for Reviews (cont'd)

"(12) In the case of review pursuant to subsections (e), (f) and (g) of section 1513 and subsections (4), (5) and (6) of section 1523, and where appropriate for other reviews--

(A) opportunity for each participant to present evidence and arguments orally and/or by written submission,

(B) opportunity for each participant to cross-examine any other participant who makes a written or oral factual allegation relevant to such a review or on which a decision might be based,

(C) the right to be represented by counsel,

(D) an administrative appeal as provided in (8) above, and

(E) judicial review, with the scope of such review to be at least as broad as that defined in the Administrative Procedure Act, 5 U.S. Code, section 706.

## V. Appropriateness Review

### A. Policy Position

The American Hospital Association supports amendments to delete appropriateness reviews from the functions of HSAs and state agencies. Agencies should not be mandated to perform functions which are beyond their capability. If, however, appropriateness review is retained in the Act, AHA urges adoption of amendments which will specifically limit application of the concept of appropriateness review and ensure its consistency with the original framework provided by the Act.

### B. Rationale

AHA suggests that the appropriateness review functions are unnecessary and should be deleted from the law. No acceptable definition of this function exists and many planning experts have expressed the viewpoint that HSAs and state agencies cannot effectively implement this provision, especially if all institutional health services must be reviewed periodically. It is AHA's view that a more effective and comprehensive planning and certification of need process can serve as the mechanisms to assess the appropriateness of facilities and services, as part of, not as an addition to, the planning process.

However, in the event that the appropriateness review provisions are not deleted from the Act, the law must be amended to reinforce the concept inherent in the original statutory language that areawide review is, in the long run, the most effective form of review. Such areawide review of selected services can be consistent with the overall framework of the comprehensive health planning legislation. The scope of the review and the procedures of the review process should be established in a way which will not overburden either the institution or the HSAs, whose funds and staffs are stretched already by their planning and project review functions. If HSAs are permitted to phase in their programs as their capabilities develop, this credibility and effectiveness will be greatly enhanced.

Appropriateness review presents additional problems for public planning bodies and for institutions. Such reviews are fundamentally different in their nature, purpose and effect from other reviews mandated by the Act. By their very nature, appropriateness reviews deal with existing services into which personal and financial investments have already been made. Such reviews, and possibly negative findings of such services, have

## V. Appropriateness Review (cont'd)

significantly greater potential to create hostility between planning bodies and institutions than reviews of proposal for new services. Similarly, institution-specific appropriateness reviews are much more likely to be taken as a derogation of institutional management, thus creating schisms which will impede the planning process which is the main focus of P.L. 93-641.

The movement of the legislation through the 93rd Congress reveals a steady erosion of the intended impact of reviews of existing services. Starting out as recertification review, with revocation of license as a possible sanction (if authorized by state law), it passed through the intermediate stage of periodic redetermination of need, with no specified sanctions, to the present form of periodic appropriateness review, again with no sanctions. However, in direct contrast to this history, HEW proposed regulations which include provisions for institution-specific as well as areawide review. Institution-specific reviews, if adopted, could encourage the imposition of both direct and indirect governmental or third party sanctions on hospitals with services characterized as inappropriate.

In 1978, both the Senate and the House bills contained modifications of the appropriateness review requirements, and if the appropriateness review provisions are not deleted entirely, AHA proposes the amendments set forth below.

C. Legislative Language

The following shows deletions from the National Health Planning and Resources Development Act required to eliminate appropriateness reviews:

## APPROPRIATENESS REVIEW

## Section 1513(g) (1) and (2)

~~"(g)(1) Except as provided in paragraph (2), each health systems agency shall review on a periodic basis (but at least every five years) all institutional health services offered in the health service area of the agency and shall make recommendations to the State health planning and development agency designated under section 1521 for each State in which the health systems agency's health service area is located respecting the appropriateness in the area of such services.~~

~~"(2) A health systems agency shall complete its initial review of existing institutional health services within three years after the date of the agency's designation under section 1515(e)."~~

## V. Appropriateness Review (cont'd)

## APPROPRIATENESS REVIEW BY STATE AGENCIES

## Section 1523(a) (6)

~~"(6) Review-on-a-periodic-basis-(but-not-less-often-than every-five-years)-all-institutional-health-services-being offered-in-the-State-and-after-consideration-of-recommendations submitted-by-health-systems-agencies-under-section-1513(g) respecting-the-appropriateness-of-such-services, make-public its-findings.~~

\* \* \*

~~"(3) A-State-Agency-shall-complete-its-findings-with respect-to-the-appropriateness-of-any-existing-institutional health-service-within-one-year-after-the-date-a-health-systems agency-has-made-its-recommendation-under-section-1513(g)-with respect-to-the-appropriateness-of-the-service.~~

"(c) If a State Agency makes a decision in carrying out a function described in paragraph (4), (5), ~~(6)-or-(7)~~ of subsection (a) which is not consistent with the goals of the applicable HSP or the priorities of the applicable AIP, the State Agency shall submit to the appropriate health systems agency a detailed statement of the reasons for the inconsistency."

The following legislative language would require improvements and modifications of appropriateness review if it is retained:

## APPROPRIATENESS REVIEW BY HEALTH SYSTEMS AGENCIES

## Section 1513(g) (1) and (4)

"(g) Except as provided in paragraph (2), each health systems agency shall review on a periodic basis (but at least every five years) ~~all those~~ institutional health services *identified in the state health plan prepared pursuant to section 1524(c)(2)* offered in the health service area of the agency, shall make recommendations to the State health planning and development agency designated under section 1521 for each State in which the health systems agency's health service area is located respecting the appropriateness in the area of such services

\* \* \*

## V. Appropriateness Review (cont'd)

*"(4) The health systems agency shall not make its recommendations respecting the appropriateness of existing institutional health services on an institution-specific basis."*

\* \* \*

## APPROPRIATENESS REVIEW BY STATE AGENCIES

## Section 1523(a) (6) and (b) (4)

*"(a) (6) Review on a periodic basis (but not less often than every five years, ~~all~~ those institutional health services identified in the state health plan prepared pursuant to section 1524(c) being offered in the state and, after consideration of recommendations submitted by health systems agency under section 1513(g) respecting the appropriateness of such services, make public its findings."*

\* \* \*

*"(b) (4) The State Agency shall not issue its findings with respect to the appropriateness of existing institutional health services in the State on an institution-specific basis."*

Other legislative language related to the issues discussed above include the following:

## PHASE IN FUNCTIONS OF HEALTH SYSTEMS AGENCIES

## Section 1513(b)

*"(b) In providing health planning and resources development for its health service area, a health systems agency shall perform, to the extent that its capabilities and approved work program permit, the following functions:*

*"(1) The Agency shall assemble and analyze data concerning--*

*"(A) the status (and its determinants) of the health of the residents of its health service area.*

*"(B) the status of the health care delivery system in the area and the use of that system by the residents of the area,*

## V. Appropriateness Review (cont'd)

"(C) the effect the area's health care delivery system has on the health of the residents of the area.

"(D) the number, type, and location of the area's health resources, including health services, manpower, and facilities.

"(E) the patterns of utilization of the area's health resources, and,

"(F) the environmental and occupational exposure factors affecting immediate and long-term health conditions."

## VI. Coordination between HSAs and Health Care Institutions

### A. Policy Position

The American Hospital Association supports amendments to the National Health Planning and Resources Development Act which will encourage coordination between the internal planning efforts of health care institutions and the areawide comprehensive health planning conducted by health systems agencies.

### B. Rationale

Experience has demonstrated that effective health planning requires extensive cooperation between the public planning agencies and the institutions whose future existence and activities are being planned. National health policy should encourage both agencies and institutions to recognize that planning is the exclusive responsibility of neither. Results for both are often directly proportional to the degree of such cooperation. Some hospital administrators and health professionals may not have a positive orientation towards planning, and some health planners lack practical experience in the management and delivery of health care resources. The public, as well as both organizations, will receive material benefits from increasing cooperation between institutions and agencies in the development of health plans, even in instances in which their conclusions may differ.

Public bodies, such as HSAs, should participate in the determination of what services and facilities are necessary to achieve the most effective and efficient levels and scope of health care for the health service area. The responsibility of any HSA, however, must stop short of determining how such services should be administered and how such facilities should be managed. In some instances, HSAs have attempted to impose on hospitals their own ideas of management techniques, even to the extreme of efforts to select hospital board members and to require medical staff appointments at HSA initiative despite the responsibility of the governing board for the quality of care at the hospital.

Hospital managers, trustees and medical staffs are best able to evaluate the needs and capabilities of their institutions and assess actions for improving them. Regulations enforced by the HSA should provide freedom for the exercise of management prerogatives to attain planning objectives.

### C. Legislative Language

To implement the policy described above, additional



## VI. Coordination between HSAs and Health Care Institutions (cont'd)

legislative language is recommended in section 1513(d) and a new subsection 1532(d) is proposed, which was derived from Section 1801 of the Social Security Act, 42 U.S.C. §1395.

## COORDINATION OF PUBLIC AND INSTITUTIONAL PLANNING

## Section 1513

"(d) Each health systems agency shall coordinate its activities with--

"(1) each Professional Standards Review Organization (designated under Section 1152 of the Social Security Act),

"(2) entities referred to in paragraphs (1) and (2) of Section 204(a) of the Demonstration Cities and Metropolitan Development Act of 1966 and regional and local entities the views of which are required to be considered under regulations prescribed under Section 403 of the Intergovernmental Cooperation Act of 1968 to carry out Section 401(b) of such Act,

"(3) other appropriate general or special purpose regional planning or administrative agencies, and

"(4) any other appropriate entity, *including entities which provide institutional health services,*

in the health system agency's health service area. The agency shall, as appropriate, secure data from them for use in the agency's planning and development activities, enter into agreements with them which will assure that actions taken by such entities which alter the area's health system will be taken in a manner which is consistent with the HSP and the AIP in effect for the area, and, to the extent practicable, provide technical assistance to such entities.

## Section 1532(d)

*"(d) Nothing in this title shall be construed to authorize any Federal or State officer or employee or any health systems agency to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any board member, officer or employee of any institution, agency or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency or person."*

## VII. Penalties for States Not in Compliance

### A. Policy Position

The American Hospital Association supports extension of the deadline for states to enact an approved certificate of need (CON) law through September 30, 1983.

### B. Rationale

By July 30, 1979, any State Health Planning and Development Agency (SHPDA) not in compliance with HEW requirements will lose federal funds to operate as a state health planning agency and HEW has indicated that it will terminate Section 1122 Program contracts. By September 30, 1980, any state which does not have a designated health planning agency-- which will then require an approved CON program-- faces loss of federal funds earmarked for support of health resources under the Public Health Service Act and various other federal acts.

To date, only eight states have a fully designated health planning agency; therefore, 42 states potentially could lose millions of federal dollars and federal funding for ongoing health programs of national priority might be affected as the deadline approaches.

The problem has not been created by hospitals' resistance to CON legislation. Only three state hospital associations have not formally endorsed passage of a CON law. Rather, the failure of states to pass such legislation seems to stem from the substantial lack of acceptance of some arbitrary and inflexible HEW regulatory requirements and from some uncertainty presented by the variety of amendments to P.L. 93-641 which were offered in the 95th Congress. Many state legislatures are unwilling to delegate the writing of such important public policy to administrative agencies and there have been few willing to accept whatever the Secretary might present.

It would be a major setback to the agencies and programs already in place to require that 42 states must pass legislation on such a complex issue within the next few months. (HEW requires two months after passage of legislation to certify its compliance with the regulations.) It is likely that neither health planning nor the other affected programs would recover from the blow imposed by complete loss of funding in any states.

## VII. Penalties for States Not in Compliance

C. Legislative Language

The following amendments are offered to accomplish the above objectives:

## Section 1521

DESIGNATION OF STATE PLANNING AND  
DEVELOPMENT AGENCIES

\* \* \*

"(d) ~~If, after September 30, 1983, upon the expiration of the fourth fiscal year which begins after the calendar year in which the National Health Planning and Resources Development Act of 1974 is enacted,~~ an agreement under this section for the designation of a State Agency for a State is not in effect, the Secretary may not make any allotment, grant, loan or loan guarantee, or enter into any contract, under this Act, the Community Mental Health Centers Act, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 for the development, expansion, or support of health resources in such State until such time as such an agreement is in effect.

## Section 1522(b)

## STATE ADMINISTRATIVE PROGRAM

\* \* \*

"(2) The requirement of paragraph (4)(B) of subsection (a) shall not apply to a State Agency of a State until the ~~expiration of the first regular session of the legislature of such State which begins after the date of enactment of this title~~ September 30, 1983.

# VIII. Provision of Free Care

## A. Policy Position

The American Hospital Association supports an amendment to clarify the obligations of health care institutions which receive certain federal funds or loan guarantees.

## B. Rationale

The purpose of this amendment is to make more reasonable the obligation of health care institutions which receive certain federal funds to make health care available to patients unable to pay.

The amendment requires that such facilities provide reasonable assurance for such health care for a period of 20 years after the approval of their funding applications if a grant, or the length of time of the loan or loan guarantee assistance. In proposed regulations governing such assurances, HEW took the statutory phrase "at all times" out of context and misinterpreted the statute to require perpetual obligations for charity care and community service. The amendment would explicitly limit the assurances to twenty years or the life of a loan, and eliminate problems with HEW misinterpretation. It also limits the facility's obligation to those persons residing or employed within its service area.

While hospitals have provided and will continue to provide services to individuals unable to pay for care, the accountability for providing a reasonable volume of uncompensated services in section 1604(b)(1)(g)(ii) should be limited to the existing 20 year period for the recovery of assistance funds found under Title VI of the Public Health Service Act.

## C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act in accord with the above policy.

## VIII. Provision of Free Care (cont'd)

## PROVISION OF FREE CARE

## Section 1604 (b) (1) (J)

"(J) reasonable assurance that ~~at-all-times-after~~ ~~such-application-is-approved~~ for a period of 20 years after the completion of such construction, modernization, or conversion with such funds, in the case of a grant, or for the length of time of the loan or loan guarantee, in the latter case, (i) the facility or portion thereof to be constructed, or modernized, or converted will be made available to all persons residing or employed in the area served by the facility and (ii) there will be made available in the facility or portion thereof to be constructed, modernized or converted a reasonable volume of services to persons unable to pay therefor and the Secretary, in determining the reasonableness of the volume of services provided, shall take into consideration the extent to which compliance is feasible from a financial viewpoint."

IX. Uniform Cost Accounting and Reporting Systems

A. Policy Position

The American Hospital Association opposes establishment of mandatory uniform accounting requirements, but supports uniform reporting of costs, rates and services.

B. Rationale

AHA supports establishment of uniform reporting, however, Section 1533(d) of the National Health Planning and Resources Development Act calls for the development by the Secretary, of uniform systems for cost accounting. A mandated system of accounting which lacks flexibility when applied to local situations cannot be implemented without impairing management responsibility and accounting innovation. The importance of a flexible accounting system, which will enable institutions to continue to adhere to generally accepted accounting principles as they evolve, cannot be overemphasized.

The American Hospital Association, therefore, recommends that Section 1533(d) and Section 1502(9) be deleted.

## X. Federal Hospital Construction Requirements

### A. Policy Position

The federal government should adopt a single set of codes and standards for the physical requirements of hospitals and other institutional providers of health care which would apply under all federal programs that stipulate compliance with facility codes and standards as requirements for participation, to which state and local governments should be encouraged to adhere as well.

### B. Rationale

The facilities in which hospital care or other institutional health care is provided are frequently subject to regulation from a multiplicity of agencies. State agencies are often granted such authority through certification or licensure laws, local authorities enforce building and sanitation codes, and federal agencies such as Medicare and the Federal Housing Authority often impose compliance with construction standards as a condition for participation in the program. These requirements are not always consistent with each other. In some cases, the institution may be able to conform to the more restrictive requirements, thus satisfying both, but in other cases it must decide which of the conflicting requirements will be satisfied, a decision usually based on the likely legal consequences of failure to satisfy the other.

This climate of multiple, often conflicting codes has sometimes resulted in frustration and confusion, not only for the institutions, but also for architects, planning authorities and even the agencies which have adopted and are charged with enforcing the conflicting codes. Further complicating the situation is the fact that new codes are constantly under development and old ones are subject to frequent revisions. Different authorities having jurisdiction often enforce different revisions. Multiple codes produce added costs for institutions, which are ultimately passed on to their patients and third party payors.

The American Hospital Association believes that the federal government should take the lead in resolving this situation. First, the federal government should require that all federal programs that include codes and standards for physical facilities as requirements for participation should have consistent or identical standards. State and local authorities and voluntary accreditation or certification bodies should be urged to adopt the federal standards as their own. Even though there

## X. Federal Hospital Construction Requirements (cont'd)

may be a demonstrated need for different emphasis in different parts of the country because of substantive geographical or environmental differences, these differences can generally be accommodated by permitting state and local authorities to impose additional but not conflicting, requirements or waivers to accommodate hazards or lack of hazards from earthquakes, hurricanes, blizzards and the like.

In development of uniform physical facility standards, maximum opportunity should be provided to all interested persons for input into the standardization of fire, safety, sanitary, electrical and other requirements. In addition, there is a need for a mechanism by which individual institutions can obtain determinations regarding appropriate requirements, use of equivalencies and adequate time allowances related to compliance with new codes. At any given time, many existing buildings are not in full compliance with all provisions of current codes. The differences between the standards met and the newest requirements are frequently small, but the cost of meeting the latest standards may be quite high, without commensurate benefit to the public interest. It must also be noted that the cheapest initial construction is not always the most economical, in view of maintenance and other operating costs which can be raised substantially as a result of initial economies in design and construction.

C. Legislative Language

The American Hospital Association supports the following amendment to the National Health Planning and Resources Development Act, adding a new Section 1602(b) to meet the above objectives.

## "General Regulations

"Section 1602(a) The Secretary shall by regulation --

\* \* \*

"(2) prescribe for medical facilities projects assisted under this title, general standards of construction, modernization, and equipment for medical facilities of different classes and in different types of location;



## X. Federal Hospital Construction Requirements (cont'd)

\* \* \*

"(4) prescribe criteria for determining the extent to which existing medical facilities are in need of modernization;

\* \* \*

"(b) In promulgating the regulations required by paragraphs (2) and (4) above, the Secretary shall --

"(1) Consult with and solicit recommendations and comments from (A) the agencies and other entities described in Section 1501(c) of title XV, (B) Federal and State agencies which have issued guidelines, recommendations, criteria, standards, or requirements respecting the physical aspects of medical facilities, (C) private entities which have promulgated standards, codes, or guidelines with respect to fire, infection, electrical or safety hazards, (D) the Joint Commission on Accreditation of Hospitals, the American Osteopathic Association and any other private entities which have established voluntary licensure or accreditation standards for health care facilities.

"(2) Within six months of enactment hereof, issue proposed regulations which will give consideration to the recommendations provided by the entities listed in (1) and which are capable of being adopted by all such agencies as uniform standards for the construction, modernization and equipment of medical facilities, whether or not such facilities are eligible for assistance under this title. Such proposed regulations shall allow a reasonable time for submission of comments by the public and the entities listed in (1).

"(3) Within one year after the date of enactment hereof, issue final regulations.

"(4) Urge adoption of the regulatory standards for construction, modernization and equipment by all agencies and entities listed in (1) to the fullest extent practicable. Such adoption shall be mandatory for all Federal agencies identified in (1) above, including without limitation, the Federal Housing Authority, the Occupational Safety and Health Administration, the Veterans Administration, the Public Health Service and the Indian Health Service.

## X. Federal Hospital Construction Requirements (cont'd)

"(5) Such standards shall make provision for the imposition by State and local agencies of additional or higher standards deemed necessary to meet substantially different local geographic or environmental conditions, such as susceptibility to earthquakes, floods and other natural phenomena, but no other inconsistent or more restrictive standards shall be imposed upon any project which is eligible for assistance under this title.

"(6) Require, to the maximum extent feasible, joint or consolidated inspection and enforcement activities by all entities described in (1).

"(7) Provide in such regulations for the issuance of advisory determinations concerning compliance with the requirements through the use of equivalencies and alternatives. Such regulations shall state specifically the degree to which existing facilities shall be required to meet new requirements and standards and shall establish appropriate time allowances for achieving such compliance. The regulations shall specify the degree to which modernization projects shall be required to meet the requirements and standards for new construction.

"(8) Provide for review on a periodic basis (but at least every three years) of the standards and requirements contained in such regulations.

## XI. Redefine Indirect Providers

### A. Policy Position

The American Hospital Association supports an amendment to restrict the definition of "indirect providers" to persons whose interests are closely allied to direct providers.

### B. Rationale

The Act's broad definition of "indirect providers" has engendered considerable uncertainty and has, in some cases, diluted or precluded the participation of individuals who are directly involved in the provision of health care. Persons who are in fact non-providers, with only coincidental or indirect ties to the health system and some who occasionally have direct conflicts with providers are presently included in the classification of "indirect providers." We urge that such persons and organizations should be qualified to serve as consumer representatives.

Accordingly, the American Hospital Association recommends that the definition of "indirect provider" not include (i) members of the immediate family of an indirect provider, (ii) any individual who receives less than one-quarter of his gross income from health care interest or direct providers, (iii) organizations which are basically concerned with education and research in aspects of particular diseases, such as the Heart Fund or the National Foundation, or (iv) insurers which do not provide health services to the public, either directly or through affiliates or subsidiaries.

### C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act to limit the definition of indirect provider:

#### INDIRECT PROVIDERS OF HEALTH CARE

##### SECTION 1531(3)

"(3) The term "provider of health care" means an individual --

\* \* \*

"(B) who is an indirect provider of health care in that the individual --

# XI. Redefine Indirect Providers (cont'd)

"(i) holds a fiduciary position with, or has a fiduciary interest in, any entity described in subclause (II), or (IV) or (V) of clause (ii);

"(ii) receives (either directly but not or through his or her spouse or other family member) more than one-tenth one-quarter of his gross annual income from any one or combination of the following:

"(I) Fees or other compensation for research into or instruction in the provision of health care;

"(II) Entities engaged-in-the-provision-of-health care-or-in which conduct such research or instruction, but not including entities which are engaged primarily in research and public education concerning special health issues or services or the detection, treatment and prevention of one or more specific diseases or physical disabilities.

"(III) Producing or supplying drugs or other articles for individuals or entities for use in the provision of or in research care.

"(IV) Entities engaged in producing drugs or such other articles.

"(V) Entities engaged in the provision of health care services to the public or to their members, subscribers or policyholders either directly or through subsidiaries or affiliates, including health maintenance organizations.

"(ii) is a member of the immediate family of an individual described in subparagraph (A) or-in-clause-(i)-or-(iv)-of-subparagraph-(B)-or

"(iv)--is-engaged-in-issuing-any-policy-or-contract-of-individual-or-group-insurance-or-hospital-or-medical-service benefits.

### XIII. Review Functions of Health Systems Agencies and Statewide Health Coordinating Councils

#### A. Policy Position

The American Hospital Association supports amendments to P.L. 93-641 to ensure that Health Systems Agencies and Statewide Health Coordinating Councils review and make recommendations and, as such, are advisory rather than decision-making bodies.

#### B. Rationale

The purpose of these amendments is to clarify that the responsibilities of the Health Systems Agencies (HSAs) and the Statewide Health Coordinating Councils (SHCCs) should be advisory only, and that their functions should be to review and make recommendations to the State Agency or to the HEW Secretary, as the case may be. We believe that these changes should be made because ambiguous wording in the current law suggests that the federal government has delegated to HSAs and SHCCs final decision-making authority over federal health grants and contracts.

Planning agencies have been given the responsibility to review proposals to determine their consistency with established areawide or state health plans, not, we believe, to approve or disapprove projects. As we view it, this difference is critical to the planning concept. It keeps the planning agencies and councils in the business of planning and out of the realm of regulation. Regulation is generally aimed at controlling or limiting, while proper planning activities may, in many cases, call for identification of need for new services.

#### C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act in accord with the above policy.

#### REVIEW FUNCTIONS OF HEALTH SYSTEMS AGENCIES

##### Sections 1513(e)(1) and (2)

"(e)(1)(A) Except as provided in subparagraph (B), each health systems agency shall review and ~~approve-or-disapprove~~ *make recommendations to the Secretary or, in the case of grants or contracts described in subparagraph (ii) of this paragraph, the appropriate State health planning and development agency* on each proposed use within its health service area of ~~federal~~ funds--

XII. Review Functions of Health Systems Agencies and Statewide Health Coordinating Councils (cont'd)

"(i) appropriated under this Act, the Community Mental Health Centers Act, sections 409 and 410 of the Drug Abuse Office and Treatment Act, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 for grants, contracts, loans, or loan guarantees of the development, expansion, or support of health resources; or

"(ii) made available by the State in which the health service area is located ~~{from an allotment to the State under an Act referred to in clause (i)}~~ for grants or contracts for the development, expansion, or support of health resources.

"(B) A health systems agency shall not review and ~~approve~~ ~~or disapprove~~ *make recommendations* on the proposed use within its health service area of Federal funds appropriated for grants or contracts under title IV, VII, or VIII of this Act unless the grants or contracts are to be made, entered into, or used to support the development of health resources intended for use in the health service area or the delivery of health services. In the case of a proposed use within the health service area of a health systems agency of Federal funds described in subparagraph (A) by an Indian tribe or intertribal Indian Organization for any program or project which will be located within or will specifically serve--

"(i) a federally-recognized Indian reservation,

"(ii) any land area in Oklahoma which is held in trust by the United States for Indians or which is restricted Indian-owned land area, or

"(iii) a Native village in Alaska (as defined in section 3(c) of the Alaska Native Claims Settlement Act),

a health systems agency shall only review and comment on such proposed use.

"(2) Notwithstanding any other provision of this Act or any other Act referred to in paragraph (1), the Secretary shall allow a health systems agency sixty days to make the review ~~and recommendations~~ required by such paragraph. If an agency ~~disapproves~~ ~~recommends against~~ a proposed use in its health service area of Federal funds described in paragraph (1)(A)(i), the Secretary may not make such Federal funds available for such use until he has made, upon request of the entity making such proposal, a review of the agency's ~~decisions~~ *recommendations*.

XII. Review Functions of Health Systems Agencies and Statewide Health Coordinating Councils (cont'd)

In making any such review of any agency's ~~decision~~ *recommendations*, the Secretary shall give the appropriate State health planning and development agency an opportunity to consider the ~~decision~~ *recommendations* of the health systems agency and to submit to the Secretary its comments on the ~~decision~~ *recommendations*. The Secretary, after taking into consideration such State agency's comments (if any), may make such Federal funds available for such use, notwithstanding the ~~disapproved~~ *recommendations* of the health systems agency. Each such decision by the Secretary to make funds available shall be submitted to the appropriate health systems agency and State health planning and development agency and shall contain a detailed statement of the reasons for the decision, *including the comments, if any, of the State agency.*"

REVIEW FUNCTIONS OF STATEWIDE  
HEALTH COORDINATING COUNCILS

Section 1524(c) (6)

"(c) A SHCC shall perform the following functions:

"(6) Review annually and ~~approve-or-disapprove~~ *make recommendations to the Secretary on* any State plan and any application (and any revision of a State plan or application) submitted to the Secretary as a condition to the receipt of any funds under allotments made to States under this Act, the Community Mental Health Centers Act, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970. Notwithstanding any other provision of this Act or any other Act referred to in the preceding sentence, the Secretary shall allow a SHCC sixty days to make the review and *recommendations* required by such sentence. If a SHCC ~~disapproves~~ *recommends against* such a State plan or application, the Secretary may not make Federal funds available under such State plan or application until he has made, upon request of the Governor of the State, which submitted such plan or application or another agency of such State a review of the SHCC's ~~decision~~ *recommendations*. If after such review the Secretary decides to make such funds available, the decision by the Secretary to make such funds available shall be submitted to the SHCC and shall contain a detailed statement of the reasons for the decision."

## XIII. Planning Grants for Health Systems Agencies

### A. Policy Position

The American Hospital Association supports an amendment to increase funding for fully designated and conditionally designated Health Systems Agencies.

### B. Rationale

We support an amendment that would increase the minimum amount a Health Systems Agency (HSA) receives for full designation and to specify that conditionally designated Health Systems Agencies are to be funded at the same levels as fully designated Health Systems Agencies. We would encourage that the amount to be awarded per person per year be increased from 55¢ to 60¢ during the fiscal year 1979, from 60¢ to 65¢ during the fiscal year 1980, and from 65¢ to 70¢ during the fiscal year 1981. These changes would reflect inflationary costs, for a total amount of \$4,500,000 unless the agency would receive a greater amount based upon population. In addition, we propose that the amount of a grant for a Health Systems Agency may not be less than \$185,000, an increase from the proposed \$175,000 (again, to reflect inflation). The purpose of the amendment is to ensure that Health Systems Agencies conditionally designated are able to perform in an effective manner. We strongly recommend that appropriations for this activity be considered in the light of a new program, which is in a critical stage of development. We urge that funding levels provide the necessary resources for the sound development of this program across the country.

### C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act in accord with the above policy:

#### PLANNING GRANTS FOR HEALTH SYSTEMS AGENCIES

##### SECTION 1516(b) (1), (2) (B), and (3)

"(b) (1) The amount of any grant under subsection (a) to a health systems agency designated under section 1515(b) shall be determined by the Secretary. ~~The amount of any grant under subsection (a) to any health systems agency designated under section 1515(e) and shall be the lesser of --~~



## XIII. Planning Grants for Health Systems Agencies (cont'd)

"(A) the product of ~~\$0.50~~ *\$0.60 during the fiscal year 1979, \$0.65 during the fiscal year 1980, and \$0.70 during the fiscal year 1981* and the population of the health service area for which the agency is designated, or

"(B) ~~\$3775070007~~ *\$4,500,000,*

unless the agency would receive a greater amount under paragraph (2) or (3).

\* \* \*

"(2)(b) The non-Federal funds which an agency may use for the purpose of obtaining a grant under subsection (a) which is computed on the basis of the formula prescribed by subparagraph (A) shall --

"(i) not include any funds contributed to the agency by any individual or private entity which has a financial, fiduciary, or other direct interest in the development, expansion, or support operation of health resources of the kind that may be within the purview of the agency's functions under subsections 1513(e), (f), and (g), and

"(ii) be funds which are not paid to the agency for the performance of particular services by it and which are otherwise contributed to the agency without conditions as to their use other than the condition that the funds shall be used for the purposes for which a grant made under this section may be used.

"(3) The amount of a grant under subsection(a) to a health systems agency designated under section 1515~~(e)~~ may not be less than ~~\$1757000~~ *\$185,000 during the fiscal year 1978, \$195,000 during the fiscal year 1979, \$205,000 during the fiscal year 1980, and \$215,000 during the fiscal year 1981.*"

#### XIV. Private Contributions to Health Systems Agencies

##### A. Policy Position

The American Hospital Association supports an amendment to increase funding for Health Systems Agencies by permitting a broadened base of non-federal funds for Health Systems Agencies activities.

##### B. Rationale

The purpose of this amendment is two-fold: First, to allow Health Systems Agencies (HSAs) to receive additional matching federal funds and second, to permit a broadened scope of non-federal funds that can be used by the HSAs for accomplishing their work programs. As an alternative to the severe limitations now stated in the law, there should be a clarification as to the sources from which a HSA cannot accept contributions because of possible benefit from an agency action. Also, if the legislation were changed to read *substantial* funds or contributions of services, this would have the effect of broadening the funding base without jeopardizing the HSA's actions. It would permit more adequate funding for HSA operations.

Every effort should be made to provide for the success of HSAs, to further develop the planning process. If only federal funds are to be used, many HSAs will not have adequate staff to perform all of their mandated functions.

##### C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act in accord with the above policy:

#### PRIVATE CONTRIBUTIONS TO HEALTH SYSTEMS AGENCIES

##### SECTION 1512(b) (5)

"(5) PRIVATE CONTRIBUTIONS.--No health systems agency may accept *more than ten percent (10%) of its operating budget or more than \$25,000 in any funds or contributions of services (other than processed data) or facilities from any individual or private entity which has a financial, fiduciary, or other direct interest in the development, expansion, or support operation of health resources within the purview of the agency under subsections 1513(e), (f) and (g) unless, in the case of an entity, it is an organization described in section 509(a) of the Internal*

## XIV. Private Contributions to Health Systems Agencies (cont'd)

Revenue Code of 1954 and is not directly engaged in the provision of health care in the health service area of the agency. *No health systems agency may accept in the aggregate from all such individuals, associations and private entities more than twenty-five percent (25) of its operating budget. For purposes of this paragraph, an entity shall not be considered to have such an interest solely on the basis of its providing (directly or indirectly) health care for its employees or health insurance benefits for enrolled subscribers."*

XV. Prohibition Against Purchasers of Health Care Being Designated as Health Systems Agency

A. Policy Position

The American Hospital Association supports an amendment to P.L. 93-641 which would eliminate the possibility that a major purchaser or provider of health services could be appointed to act as a health systems agency, thus avoiding a potentially major conflict of interest.

B. Rationale

The National Health Planning and Resources Development Act of 1974 currently permits designation as health systems agencies of not-for-profit corporations, public regional planning bodies or units of local government. Entities which are or operate educational institutions are prohibited from being so designated.

Many units of local government are major providers or purchasers of health care, frequently operating municipal or county hospitals or being charged with responsibility for administering and funding Medicaid or welfare programs under which health services are provided to segments of the population. If such government agencies should be appointed as health systems agencies or be allowed to control health systems agencies, a serious conflict between their interest as planners and their interest as purchasers of health care would result. Clear indication is provided in the statute that Congress did not intend this result; a multitude of safeguards are provided to ensure that health systems agencies would not be dominated by provider or purchaser interests.

American Hospital Association proposes that the statute be amended to prohibit local government agencies and private organizations that are major purchasers or providers of health care from being designated as health systems agencies. This will prevent the possibility that decisions about resource allocations will be made by those with vested interest in the outcomes.

C. Legislative Language

The following legislative language is proposed:

XV. Prohibition Against Purchasers of Health Care Being  
Designated as Health Systems Agency (cont'd)

"Health Systems Agencies

\* \* \*

"Sec. 1512.

"(b)(1) Legal Structure.-- A health systems agency for a health service area shall be --

\* \* \*

"A health systems agency may not be an educational institution or operate such an institution, *nor may a health systems agency be a substantial purchaser or provider of health care nor control or operate an entity which is a substantial purchaser or provider of health care.*

XVI. Transfer of Health Services Development Grants Functions to State Agencies

A. Policy Position

The American Hospital Association supports amendments that would convert the Area Health Services Development Fund to the State Health Services Development Fund, to be administered by the designated state agency.

B. Rationale

The purpose of these amendments is to eliminate the grant-making function from the functions mandated for a Health Systems Agency (HSA). Instead, HSAs would solicit proposals from individuals, public and non-profit private entities. These proposals would assist the HSAs in planning and developing projects and programs which they deem necessary for the achievement of the goals described in their health systems plans and annual implementation plans. The proposals would then be submitted to the State Health Planning and Development Agencies, which would be responsible for selecting and funding the proposals. The financial support would be derived from the State Health Services Development Fund established pursuant to section 1640.

AHA endorses federal funding support for developmental assistance, which we regard as a highly desirable function. However, the developmental program activity should be the responsibility of a state level agency which would be able to determine statewide priorities and more effectively allocate federal funds. This would also help avoid a conflict for HSAs in having to review objectively a proposal which was planned with area health services development funds made available directly by the HSA. This problem would be eliminated if development funds were specifically limited to planning for projects already endorsed by the HSA or to planning activities of the kind that would not result in proposals requiring HSA review. There are a number of safeguards which may be included, such as a provision that the HSA and the State Agency must agree before projects become funded. The role of the Statewide Health Coordinating Council might well be that of a sounding board.

C. Legislative Language

The following is proposed legislative language to amend the National Health Planning and Resources Development Act in accord with the above policy:

XVI. Transfer of Health Services Development Grants Functions to State Agencies (cont'd)

FUNDING OF PROPOSALS BY STATE AGENCIES

Section 1523(a)(1)

"SEC. 1523. (a) Each State Agency of a State designated under section 1521(b)(3) shall, except as authorized under subsection (b), perform within the State the following functions:

"(1) Conduct the health planning activities of the State and support the implementation of those parts of the State health plan (under section 1524(c)(2)) and the plans of the health systems agencies within the State which relate to the government of the State and to the health care delivery system in the State, through the agencies of State government and through the State Health Services Development Fund established pursuant to section 1640, which have received review and recommendation by the HSA or are not subject to such review and recommendation.

ELIMINATION OF THE GRANT MAKING FUNCTION OF HEALTH SYSTEMS AGENCIES

Section 1513(c)(3)

"(c) A health systems agency shall implement its HSP and AIP, and in implementing the plans it shall perform at least the following functions:

\* \* \*

"(3) The agency shall, in accordance with the priorities established in the AIP, ~~make grants to public and nonprofit private entities and enter into contracts with solicit proposals~~ from individuals and public and nonprofit private entities to assist them in planning and developing projects and programs which the agency determines are necessary for the achievement of the health systems described in the HSP. *The proposals shall be submitted with the agency's review and recommendations to the State Agency. Such grants and contracts shall be made from the Area Health Services Development Fund of the agency established with funds provided under grants made under section 1640. No grants or contract under this subsection may be used (A) to pay the costs incurred by an entity or individual in the delivery of health services (as defined in regulations of the Secretary), or (B) for the cost of construction or modernization of medical facilities.* ~~No single grant or contract made or entered into under this paragraph shall be available for obligation beyond the one year period beginning on the date the grant or contract was made or entered into. If an individual~~

XVI. Transfer of Health Services Development Grants Functions to State Agencies (cont'd)

~~or-entity-receives-a-grant-or-contract-under-this-paragraph for-a-project-or-program;-such-individual-or-entity-may receive-only-one-more-such-grant-or-contract-for-such-project or-program."~~

STATE HEALTH SERVICES DEVELOPMENT FUNDS

Section 1640

"Part F -- Area State Health Services  
Development Funds

"Development Grants for Area State  
Health Services Development Funds

"SEC. 1640. (a) The Secretary shall make in each fiscal year a grant to each *State health planning and development agency in each State, in which there is at least one health systems agency--*

"(1) with which there is in effect a designation agreement under section 1515(c),

"(2) which has in effect an HSP and AIP reviewed by the Statewide Health Coordinating Council, and

"(3) which, as determined under the review made under section 1535(c), is organized and operated in a manner prescribed by section 1512(b) and is performing its functions under section 1513 in a manner satisfactory to the Secretary,

to enable the *State* agency to establish and maintain an-Area State Health Services Development Fund from which it may make grants and enter into contracts in accordance with section ~~1513(e)-(3)~~ 1523(a)(1).

"(b)(1) Except as provided in paragraph (2), the amount of any grant under subsection (a) shall be determined by the Secretary after taking into consideration the population ~~of-the health-service-area-for-which-the-health-systems-agency-is designated within the State~~, the average family income of the *area State*, and the supply of health services in the *area State*.

"(2) The amount of any grant under subsection (a) to a *health-systems State* agency for any fiscal year may not exceed the product of \$1 and the population of the *health-service-areas for-which-such-agency-is-designated State*."




**AMERICAN HOSPITAL ASSOCIATION**

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STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION  
 TO THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
 OF THE  
 SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES  
 ON S.544, HEALTH PLANNING AMENDMENTS OF 1979

March 21, 1979

The American Hospital Association represents over 6,400 member institutions, including most of the nation's hospitals, as well as long-term care and mental health facilities, hospital schools of nursing, and over 27,000 personal members. We are pleased to again present our views and comments on proposed amendments to P.L.93-641 which are before the Committee as S.544, the "Health Planning Amendments of 1979."

Our Association supported the enactment and implementation of P.L.93-641 and we endorse the extension of the Act. We are committed to the development of an effective health planning process because it is consistent with our goal of improving access to quality health care services. As debate continues over other approaches to reducing the rate of increase in health care costs, there can be little argument that the health planning process is making substantial progress toward the same end through rational planning for the allocation of health care resources.

Because of its important role in the provision of health care services, the hospital has a special responsibility to plan effectively. Therefore, it is particularly important that hospitals be represented and participate in the planning process at all levels--local, state and national. We support and encourage the development by HEW of sound and

equitable health planning guidelines and methodologies to assist the planning agencies at the local and state levels, without imposing rigid formulas from the top. The health planning process can work most effectively through a "bottom-up" approach. Health planning must be based on health needs identified by HSAs, consumers, and providers. The methodology of planning must take into account a variety of factors which apply to the planning area, including the incidence and prevalence of disease, the socio-demographic characteristics of the population, the present capabilities of the health care system and the attitudes of the community regarding the delivery of health care services. Therefore, the approach to planning must provide for a clear-cut distinction between health planning at the local level, health planning and regulation on the state level, and the role of the federal government in providing support at the national level.

Finally, we would emphasize that the framework of health planning may evolve into a meaningless, and perhaps even counter-productive process, if it becomes incapable of implementation. Limitations of funding, staffing, the availability of data, and the state of the art in evaluating medical care and medical services affect the extent to which planning agencies can be expected to expand their activities. The AHA firmly believes that a broad framework for health planning must allow the development of programs only as capabilities develop and as relationships between providers and external planning bodies mature. Otherwise, both the credibility and the effectiveness of the process is diminished. The AHA believes that amendments to P.L.93-641 at this time should strengthen the fundamental aspects of planning and encourage progress toward more comprehensive activities as cooperation develops, but should not over-extend the resources and capabilities of either planners or providers.

We believe that many of the provisions of S.544 will substantially enhance the planning processes established under P.L.93-641. We would like to comment on some particular

areas of agreement and suggest changes in areas of disagreement in the remainder of our comments. We will conclude with some suggestions for further amendments which we believe are consistent with the interests of the Committee in strengthening the planning process. The AHA's complete amendment package is provided to the Subcommittee with this statement.

#### I. Clarification of Relationship Between National Guidelines and Local Planning

The AHA strongly supports the provision of Section 119 which would eliminate the requirement that the local Health System Plans be "consistent with" the National Guidelines. This requirement as interpreted through the regulations of HEW has caused considerable confusion in the field in that it tends to negate the concept of "bottom-up" planning. This concept was the clear intention of P.L.93-641, as expressed in the requirement of Section 1513(b)(2)(B) that health planning be "responsive to the unique needs and resources of the (health service) area." While the guidelines are clearly to be useful tools for local planners, their use as inflexible, mandatory standards serve only to impede HSAs in serving local health planning needs. We urge adoption of this amendment which would reinforce the balance between local and national authority intended by the original enactment.

#### II. Certificate of Need (CON)

We support extension of certificate of need coverage to acquisitions of major medical equipment outside of the hospital setting. We note, however, that Section 136 replaces the more comprehensive requirement in S.2410 last year (approved by the Senate) with one affecting only equipment which will be used to treat hospital inpatients outside of the hospital. This provision can do little to alleviate the concerns which underlied the original proposal for the extension. For example, it will not stem the well-publicized proliferations of CAT scanners into non-institutional settings, since these scanners are also used extensively for the diagnosis of outpatients. As outpatient usage is expanded into non-institutional settings, average operating costs in all

settings rise. In light of the national debate over health care costs, we urge that the Committee extend the coverage of CON programs to all acquisitions of major medical equipment irrespective of ownership or location.

The AHA also supports the intention of Section 142 of the bill which would broaden the definition of "institutional health services" for state certificate of need requirements. Again, we would urge for the reasons stated above that additional language in this section be included to make the definition inclusive of services otherwise covered regardless of ownership or location. We would add, however, that the \$50,000 annual operating cost threshold is too low. We recommend that the threshold be set at \$150,000. We believe the intention of Section 1531(5) will still be effectuated at this higher figure and will avoid the difficulties indicated.

We also urge the Committee to recognize, within the definition of Section 1531(5), the distinction between a "new institutional service" and the modernization of existing services. A substantial proportion of capital expenditures by hospitals is for the replacement of existing facilities and equipment because of depreciation or obsolescence. Obviously, in making such a purchase, the most-improved version of such equipment should be purchased in order to obtain highest value. In some instances, state or area agencies have insisted on reviewing even expenditures of less than the statistical CON threshold because the latest model of the equipment will perform more functions than the one being replaced. Interpreting this replacement as a "new" service is expensive to both institutions and agencies and tends to hinder improvement of both the quality and cost-effectiveness of health care services. We suggest the addition of language to Section 1531(5) to clarify this situation.

Finally, we must object to the amendments proposed in Section 148(a) and (b) of the bill which would include cost and quality elements among the criteria for area and state agency reviews. Certainly these two elements are of critical importance in the provision

of health services. However, we sincerely believe that application of these criteria to project reviews will result in the frustration of planning efforts because most planning agencies have neither the staff time nor expertise to evaluate such factors for every applicant, especially in view of cost variances between institutions caused by a complex matrix of factors, including differences in medical staff practice patterns, intensity of services, patient mix, capacity, and age and condition of the physical plant.

Therefore, we urge the Committee to delete Section 148(a) and (b) from the bill in order to avoid entangling the planning process in administrative and legal burdens which can only lessen its credibility.

### III. Institutional Representation on Planning Bodies

Useful health care planning requires cooperation among all affected components of the community, including consumers, government, physicians, institutions and other providers. Hospitals are a particularly complex component of the health care system, in which many apparently diverse interests must be reconciled. Hospital administrators must consider the needs and interests of the institution's medical staff, its nurses, its technicians and other practitioners, its non-professional employees and, above all, its patients. Consequently, the hospital administrator's knowledge and experience is invaluable at all levels of planning--local, state and federal--and the expanded use of this expertise in the planning process would improve the acceptability of planning and review decisions.

The principal impact of the statute is upon providers of major institutional services--for the most part, hospitals. However, as it is now written, there is no provision to ensure any representation of hospital administrators at all levels of the planning structure. An agency board devoid of such representation might fail to consider important issues in discharging its planning and review functions, with the risk of turning the entire process into a confrontation between adversaries, instead of a cooperative effort to solve community problems. Consequently, provisions must be included in the Act to

provide specifically for the inclusion of hospital administrators on planning bodies and advisory committees.

AHA supports the expansion of the National Council and the concomitant inclusion of the Assistant Secretary for Rural Development and representatives of rural and urban medically underserved areas, as provided in Section 101 of S.544. We urge, in addition, that the number of providers be increased, in order to maintain a balance between consumer and provider members; and that the inclusion of a hospital administrator, a concept which was supported last year during Senate debate, be ensured by specific language.

On the state level, we urge that Section 1524(b)(1)(c) of P.L.93-641 be amended to increase the proportion of direct providers on the Statewide Health Coordinating Council from one-third to one-half of all provider representatives, and to ensure that at least one of the provider representatives shall be a representative of hospital administration.

The AHA supports the changes proposed in Sections 110-114 of S.544 which clarify the restrictions on representation on local planning bodies. We especially endorse Section 111(a) which permits participation on HSA boards by providers whose principal place of business is within the service area and Section 114(b) which establishes that ex-officio members shall be non-voting. The latter concern has been especially troublesome with regard to representatives of federal facilities. It is inequitable that such ex-officio members have voting power when their facilities are not formally accountable under the planning law.

Section 113 increases the number of provider categories. While it is worthwhile to have representation of a broad range of interests, we believe that there should be a concomitant amendment guaranteeing that at least one provider member shall represent hospital administration. AHA also suggests that at least one-half of the provider

members should be direct providers, in keeping with our concerns outlined at the beginning of this section.

AHA also supports Section 141(b) of the bill which clarifies that consumers who serve on governing boards of other health organizations or agencies should be considered consumers and not indirect providers.

The Act's broad definition of "indirect providers" has engendered considerable uncertainty and has, in some cases, diluted or precluded the participation of individuals who are directly involved in the provision of health care. Persons who are in fact non-providers, with only coincidental or indirect ties to the health system and some who occasionally have direct conflicts with providers are presently included in the classification of "indirect providers." We urge that such persons and organizations should be qualified to serve as consumer representatives.

Accordingly, the American Hospital Association recommends that the definition of "indirect provider" not include (i) members of the immediate family of an indirect provider, (ii) any individual who receives less than one-quarter of his gross income from health care interest or direct providers, (iii) organizations which are basically concerned with education and research to aspects of particular diseases, such as the Heart Fund or the National Foundation, or (iv) insurers which do not provide health services to the public, either directly or through affiliates or subsidiaries.

#### IV. Due Process Guarantees

The AHA supports those amendments which would ensure providers the protections of due process during the course of reviews conducted under the Act, especially those which are regulatory or quasi-judicial. These provisions are necessary to protect the legal and economic rights of parties and to provide a sense of orderliness and fairness which are often absent from the present system, both in project review and in planning.

Specifically, AHA endorses the notice, hearing, and appeal provisions of Sections 117, 133, 143, 144, 145, 146, and 147. We especially commend Section 144(a), eliminating the "pocket veto" provision of the law, which encourages unnecessary delay and secrecy and substantially handicaps public understanding of the planning process.

The Association would like to recommend three additional due process guarantees that should be incorporated into P.L.93-641 and which would complement the changes proposed in S.544.

1. Section 1532(b) of the Act should guarantee the opportunity for all affected persons to be represented by counsel in reviews pursuant to Sections 1513(e), (f), and (g) and 1523(4), (5), and (6) and in other procedures where appropriate. This would better protect the cross-examination guarantees proposed in Section 144(c) of S.544.

2. The AHA believes that any affected party should have the right of an administrative appeal to an independent hearing officer (or other agency as provided by state law) of a final decision of a state agency. Consequently, we would delete the restrictive provisions of Section 1522(b)(13) and add a broader guarantee under Section 1532(b) of P.L.93-641.

3. The guarantee of judicial review should be made available to persons adversely affected by decisions of RSAs pursuant to Sections 1513(e), (f), and (g).

Finally, we would like to point out that the scope of judicial review proposed in Section 133 of the bill is exceedingly narrow. Experience discloses no reason for granting a more restricted scope of review to state agency decisions than is generally available for review of federal agency decisions under the Administrative Procedure Act (APA) and the comparable statutes or common law of most states. We urge the Committee to adopt language which will permit the same scope of review of state agency decisions as that generally available with respect to other administrative agencies in the state or, in the alternative, that available under the APA.



#### V. Appropriateness Review

The American Hospital Association advocates the deletion of appropriateness review from the functions of HSAs and state agencies. No acceptable definition of this function exists and many planning experts have expressed the viewpoint that HSAs and state agencies cannot effectively implement this provision, especially if all institutional health services must be reviewed periodically. Such reviews are fundamentally different in their nature, purpose, and effect from other reviews mandated by the Act. By their nature, appropriateness reviews deal with services into which personal and financial investments have already been made. Such reviews have significantly greater potential to interject an adversary relationship into the planning process than reviews of proposals for new services. Extended legal and administrative burdens on the planning process are likely to result, reducing the effectiveness of the process as a whole. We believe that an overall assessment of facilities and services is a part of the preparation of a Health Systems Plan. A more effective and comprehensive planning and certification of need process can serve as the mechanism to assess the overall appropriateness of facilities and services to part of, rather than as an addition to, the planning process.

Should appropriateness review not be deleted from the Act, the law must be amended to reinforce the concept inherent in the original statutory language that areawide review is the most effective form of appropriateness review. Such areawide review of selected services can be consistent with the overall framework of the comprehensive health planning legislation. The scope and procedures of the review must be established in a way which will not overburden either the institutions or the HSAs, whose funds and staffs are stretched already by their planning and project review activities. If HSAs are permitted to phase in their programs as capabilities permit, their credibility and effectiveness will be greatly enhanced.

In this context, AHA believes that Section 124 of the bill, which focuses the scope of appropriateness review to those services identified in the State Health Plan, is a proper measure. We would urge that the same limitation apply to state agencies under Section 1523(a) of the Act. We would further urge that language be added to Sections 1513(g) and 1523(b) to clarify that appropriateness review recommendations are not to be made on an institution-specific basis.

Finally in this regard, we would point out, as detailed in Section II of these comments, that we do not believe that HSAs generally possess the staff or the resources to review the cost-effectiveness and the quality of services being delivered by any particular institution, as suggested in Section 123(a) of the bill. We strongly oppose this provision and believe it would tend to discredit the planning process through the controversy which would follow its effectuation.

#### VI. Coordination Between HSAs and Health Care Institutions

AHA supports Section 122 of the bill which requires that planning agencies coordinate their activities with state rate review agencies. Such a requirement will further encourage the coordination of internal institutional planning and areawide health planning. However, we believe that further direction toward cooperative effort in P.L.93-641 is necessary.

Experience has demonstrated that effective health planning requires extensive cooperation between the public planning agencies and the institutions whose future existence and activities are being planned. National health policy should encourage both agencies and institutions to recognize that planning is the exclusive responsibility of neither. Results for both are often directly proportional to the degree of such cooperation. Both possess experience and skills often not shared by the other party.

The activity of any HSA, however, must stop short of determining how services should be administered and how facilities should be managed. In some instances, HSAs have attempted

to impose upon hospitals their own ideas of management techniques, even to the extreme of efforts to select hospital board members and to require medical staff appointments at HSA initiative despite the responsibility of the governing board for the quality of care at the hospital.

We propose amendments to Sections 1513(d) and 1532 which would require HSAs to coordinate their activities with institutional providers of health care and also prohibit HSAs from exercising any supervision or control over the practice of medicine, the selection or tenure of institutional board members, trustees, officers or employees, or the direct administration and operation of an institution.

#### VII. Penalties for States Not in Compliance

We agree with the intent of Section 132 of the bill which would mitigate the impact of the penalty provision in Section 1521(d) of P.L.93-641 over the next three years. To date only eight states have been fully designated under the planning law. The problems at the state level stem in part from a reluctance on the part of the states to accept rigid HEW guidelines and the uncertainty attendant upon the failure of the 95th Congress to enact a three-year extension of the Act. The interests of rational health planning require an extension of time for states to develop their planning and regulatory structures required by the law.

However, loss of even partial P.H.S. program funding pursuant to Section 1521 could be a major setback to the health programs of many states. AHA proposes that no sanction be imposed prior to October 1, 1983. Further, we suggest that the deadline in Section 1523(b) for state agency implementation of a CON law also be extended to September 30, 1983.

#### VIII. Conflict of Interest

Section 104 of the bill would require HSAs and SHCCs to adopt procedures to prevent conflicts of interest involving matters before these bodies. A definition is proposed

for such conflicts, and the Secretary is required to promulgate implementing regulations that define procedures and conditions under which a conflict of interest warrants the exclusion of an individual from the review process. AHA supports the disclosure of conflicts of interest by members of HSAs or SHCCs or their employees, and, in such cases, their exclusion from participation in the review process. The amendment in Section 104 includes as a conflict any substantial direct or indirect "competitive... interest" in any matter "regarding any person, institution, organization, or other entity."

While we agree that no individual should participate in a proceeding in which the individual is the sponsor of an application or has an interest in a directly competing proposal for the same equipment or service, we are concerned that Section 104, as currently drafted, leaves open the possibility that a "competitive" interest could be so broadly construed as to unnecessarily limit provider participation in review activities. We therefore recommend to the Committee that this provision be redrafted to avoid this problem.

The AHA also supports the addition of language to Section 1512(b) to eliminate the possibility that a major purchaser or provider of health services could be appointed to act as a health systems agency, thus creating a potentially major conflict of interest. Many units of local government are major providers or purchasers of health care, frequently operating municipal or county hospitals or being charged with responsibility for administering and funding Medicaid or welfare programs under which health services are provided to segments of the population. The potential conflict between the government as planner and the government as provider or purchaser is clear. The multitude of safeguards in P.L.93-641, designed to assure that agencies would not be dominated by provider or purchaser interests, indicate that Congress did not intend this result.

AHA proposes that the statute be amended to prohibit local government agencies and private organizations that are major purchasers or providers of health care from being designated as HSAs.

#### IX. Planning Grants to HSAs

AHA supports the increased funding levels for HSAs contained in Section 129 of the bill. Higher funding levels will improve HSA performance and program development. Only if HSAs have adequate resources can they perform their jobs properly and establish the credibility of the planning process.

In this regard, AHA proposes two additional amendments which would further the development of HSAs through financial assistance.

1. AHA supports an amendment to Section 1516(b) of P.L.93-641 to specify that conditionally designated HSAs shall be funded at the same level as their fully designated counterparts. Conditionally designated agencies are, by definition, in a developmental stage and their effective performance and progress toward full designation depend on adequate resources.

2. We support an amendment to Section 1512(b)(5) to increase funding for HSAs by permitting a broadened base of non-federal funds. As an alternative to the severe limitations now imposed by the law, there should be a clarification as to the sources from which an HSA cannot accept contributions because of potential conflicts of interest.

#### X. Other Sections of S.544

We would like to address our comments in this section to further subject areas of S.544 for which the AHA amendment package does not include specific comments.

##### Program for Voluntary Reductions In Service and Capacity

Section 206 of S.544 would amend Title XVI to provide three forms of assistance to hospitals to incentives for discontinuance of unneeded services or facilities.

The first would provide financial assistance to hospitals which discontinue all inpatient services, if these services are determined by the planning process to be unneeded. It would provide funds to retire existing indebtedness attributable to equipment or facilities. In addition, it would provide an incentive payment for certain limited purposes. We support this provision and urge that it be retained in the final bill.

A second form of incentive proposed under this amendment is intended to encourage discontinuance of unneeded services in an identifiable unit of a hospital. This provision seems to deal with the issue less adequately than the support offered for total closure of inpatient services. Specifically, there is no provision for debt retirement. This deficiency, in combination with the limitation on the level of incentive payment, may prevent a hospital from meeting the costs of closure. We recommend that the financial support for the costs of closure of an identifiable unit of a hospital be similar to the provisions we have supported for the closure of all inpatient services of a hospital.

The third form of incentive proposed would encourage the conversion of an identifiable part of a hospital which is underutilized into a needed long term care facility, ambulatory care facility, or any other service designated by the Secretary and approved by the planning process. The payment would amount to 50 percent of the costs of conversion. We strongly support this provision.

#### Staff Expertise

AHA supports Section 105, which would require that HSA staff expertise include financial and economic analysis and public health issues. The addition of this requirement will strengthen the planning process, since rational planning decisions can only be made by planning body members with adequate staff support.

We suggest, further, that Section 105 be modified to include a requirement that HSA staff expertise also encompass knowledge of hospital administration, inasmuch as a full

understanding of the complexities of operating and financing a hospital is essential for the proper analysis of issues involving health care institutions.

#### Health Plan Requirements

Section 118 of the bill would make several requirements related to Health Systems Plans and State Health Plans. The AHA opposes Subsections (b) and (e) of this section.

Subsection 118(b) would require that state CON decisions be consistent with the State Health Plan. We believe this provision is too restrictive because one cannot reasonably expect that all justifiable needs will be anticipated in the Plan. We recommend that flexibility be allowed, so that a state agency can grant a CON in a case of demonstrable need, though it may not be specifically included in the State Health Plan.

Subsection 118(e) would require that the State Health Plan must be completed before a state agency can receive grants under Section 1525 of the Act. We agree that a completed State Health Plan is essential to a proper planning process. However, this proposed change could place states in an untenable situation by denying them the resources required to produce a Plan on the basis that they do not already have one. The existing authority in Section 1525(b) can be used effectively to ensure timely completion of State Health Plans, since it already permits HEW to restrict its grant activities to fit particular situations.

#### Public Hospital Modernization

Section 204 of the bill would extend and increase the authorizations in Section 1625(d) of the Act, under which construction and modernization project grants are provided to public hospitals to eliminate or prevent safety hazards or to avoid noncompliance with state licensure or voluntary accreditation standards.

AHA strongly supports the expansion of this needed program of assistance to public hospitals, for which funds are sorely needed. We would also recommend that the scope

and authorization for this program be expanded to include justified projects in private not-for-profit facilities. Such a grant program should certainly be limited to assisting projects where both the need for structural improvement and the financial capability of the institutions make such support imperative. For example, in many urban and rural poverty areas there are both private not-for-profit and public hospitals providing essential health care services. These institutions are incapable of mobilizing the necessary financial resources for the purposes identified in Section 1625. In the case of private hospitals, some are unable to qualify for a loan because of their precarious financial position. In these instances, the availability of some government grant funds is crucial. Therefore, we applaud Section 204, and, further, we recommend an increase in the authorization levels in this section, together with the inclusion of eligibility of private not-for-profit facilities for this targeted grant program.

#### XI. Other Amendments Recommended by AHA

The AHA supports amendments to P.L.93-641 in five areas not specifically addressed in S.544, which are described below.

A. Provision of Free Care. Under the original Hill-Burton Act, each applicant for a hospital construction grant could be required to assure that a reasonable volume of hospital services, subject to financial feasibility, would be made available by the hospital to persons unable to pay--a provision still in effect. The statute also included a provision that, if any hospital receiving assistance under the program ceased operation or was converted from a nonprofit facility within 20 years from the completion of construction, the United States would be entitled to recover a portion of the assistance provided. No repayment was required beyond the 20 year period.

Some 25 years after the passage of the Hill-Burton Act, regulations were promulgated by HEW to quantify the "reasonable" volume of free services required to be provided by



Hill-Burton assisted facilities. Under these regulations, hospitals in receipt of Hill-Burton assistance were required to provide charity care for a period of 20 years from the date the assistance was provided. The methods established by the regulations for determining the required annual amount of free care resulted in the potential payback over 20 years of twice the amount of the original assistance.

Despite the fact that Title XVI contains the same right of recovery, HEW has misinterpreted the statutory requirement to require perpetual obligations for charity care and community service. To clarify this situation, we recommend that the Committee adopt our amendment to Section 1604 to explicitly limit the assurances to 20 years or the life of a loan. This clarification is supported by the 20 year statutory limit on HEW's right of recovery for diversion of funds to an unauthorized purpose, common understanding since the inception of the Hill-Burton program in 1946, and by a U.S. Court of Appeals decision that recognized such limitation.

B. Uniform Cost Accounting and Reporting. The AHA opposes establishment of mandatory uniform accounting requirements, but supports uniform reporting of costs, rates and services. However, Section 1533(d) of the National Health Planning and Resources Development Act calls for the development by the Secretary of uniform systems for cost accounting. A mandated system of accounting which lacks flexibility when applied to local situations cannot be implemented without impairing management responsibility and accounting innovation. The importance of a flexible accounting system, which will enable institutions to continue to adhere to generally accepted accounting principles as they evolve, cannot be overemphasized.

AHA, therefore, recommends that Section 1533(d) and Section 1502(9) be deleted.

C. Federal Hospital Construction Standards. Health care facilities are frequently subject to the construction standards of a multiplicity of agencies. Federal agencies, such as HEW, the Department of Labor, and the Department of Housing and Urban Development, often require compliance with construction standards as a condition for participation in their programs or for financial assistance. State and local agencies also impose standards through various certification or licensure laws and building, fire, and sanitation codes.

Further complicating the situation is the fact that new codes are constantly under development and old ones are subject to frequent revisions. Different authorities often enforce different revisions. Multiple codes produce added costs for institutions which ultimately must be passed on to patients and third-party payers.

The Association believes that the federal government should take the lead in cooperation with AHA and other appropriate organizations in resolving this situation by developing a single set of codes and standards for the physical requirements of hospitals and other institutional health facilities which would apply to all federal programs and to which state and local governments would be encouraged to adhere.

In regard to state and local authorities, there may be, in some instances, a demonstrated need for different emphases in different parts of the country because of geographical or environmental distinctions. These distinctions can generally be accommodated by permitting state and local authorities to impose additional, but not conflicting, requirements to account for hazards from earthquakes, hurricanes, floods, etc.

D. Review Functions of HSAs and SHCCs. The AHA recommends amendments to Sections 1513(e) and 1524(c) that are designed to clarify the advisory roles of HSAs and Statewide Health Coordinating Councils (SHCCs) with regard to review of applications for various types of federal funds. Current law suggests that the federal government has delegated to HSAs and, in some instances, to SHCCs, the decision-making authority over applications for

federal health grants to local entities or to states. We do not believe that this is, or should be, the practice.

Planning agencies have been given the responsibility to review proposals to determine their consistency with established areawide or state health plans, not, we believe, to approve or disapprove projects. The distinction which we propose between advisory and decision-making rules would keep planning agencies in the business of planning and out of the realm of regulation. The final decision regarding federal project grants rests with the responsible state agency, taking into account the recommendations of local planning units. We would amend the language in these sections which suggest otherwise.

E. Health Services Development Grant Functions of HSAs. AHA endorses federal funding support for developmental assistance, which we regard as a highly desirable function. However, we believe that the provisions of P.L.93-641 which would provide area health services development funds to HSAs should be changed. This authority dilutes the focus of HSA planning activity by extending the functions of the agency to grant making and grant managing. This should be the responsibility of the state agency which would be able to determine statewide priorities and more effectively allocate federal funds. This would also help avoid a conflict for HSAs in having to review objectively proposals which were planned with area development funds awarded by the HSAs.

### XIII. Conclusion

The American Hospital Association continues to support the development of sound health planning through the successful implementation of the National Health Planning and Resources Development Act of 1974. We stand ready to assist the Committee in any way we can to modify the Act to assure such development.



## AMERICAN MEDICAL ASSOCIATION

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JAMES H. SAMMONS, M.D.  
Executive Vice President  
(751-6200)

March 21, 1979

The Honorable Edward M. Kennedy  
Chairman  
Subcommittee on Health and Scientific Research  
Committee on Labor and Human Resources  
United States Senate  
Washington, D.C. 20510

Re: S. 544, "The Health Planning  
Amendments of 1979"

Dear Chairman Kennedy:

The American Medical Association submits its comments regarding S. 544, "The Health Planning Amendments of 1979".

There are many areas of PL 93-641 that need change before community-based health planning can become a reality. S. 544 makes some of these changes and we have attached to our statement a summary of other amendments believed necessary. We believe that our amendments are fundamental to making the health planning system more responsive to the needs of each community. By being so responsive, health planning can better achieve desirable objectives.

In our statement we have sought to address certain important areas of S. 544. We have pointed out our opposition to extension of certificate-of-need to physicians' offices and to unfair advantages for HMOs. We have also pointed out our support for programs providing appropriate incentives for closures and conversions. Our primary concern on these stands is the maintenance of access to quality health care.

We are prepared to meet with your Subcommittee or the full committee to discuss the specific language of our proposals.

Sincerely,

A handwritten signature in dark ink, reading "James H. Sammons".

James H. Sammons, M.D.

JHS:sr

Attachment

STATEMENT  
of the  
AMERICAN MEDICAL ASSOCIATION  
to the

Subcommittee on Health and Scientific Research  
Committee on Labor and Human Resources  
United States Senate

Re: S. 544, The Health Planning Amendments of 1979

March 21, 1979

The American Medical Association supports community-based health planning as an important element in the efficient, effective delivery of high quality medical care to patients. The distribution of health resources must be a rational process in order that the availability and quality of care not be adversely affected by inappropriate decisions concerning the need for services.

Health planning must be flexible enough to accommodate the different medical needs of individual patients and to insure the availability of high quality medical care for all persons who need it. This can best be achieved by placing the planning authority and power at the local level and by insuring that those most directly involved in, and knowledgeable about, the use of medical services at the local level have the basic responsibility for making decisions regarding the quality, distribution and availability of services.

PL 93-641, as presently written and implemented, does not meet these standards and unless corrective action is taken by the Congress, the law should be repealed.

S. 544 does contain some needed improvements to the health planning process; however, it does not go far enough and we offer additional amendments (description attached) that would more nearly achieve community-oriented health planning. Further, there are other provisions which we believe would perpetuate some of the problems now in PL 93-641. We urge Congress to reject any proposal that would inhibit the delivery of high quality medical care or that would discourage the participation of any interested parties in the health planning process.

Three major proposals found in S. 544 must be addressed. These are the extension of certificate-of-need to physicians' offices, the conversion or discontinuance of health facilities, and the certificate-of-need process as it affects health maintenance organizations.

#### Coverage of Physicians' Offices Under Certificate-of-Need

S. 544 would require extension of certificate-of-need to the physician's office by covering purchases of "diagnostic or therapeutic equipment" when the state planning agency has determined that the equipment will be used on a regular basis for inpatient care. Such extension of the planning law must be examined carefully.

The language of the provision requires that each state adopt it as a minimum part of its CON law. The decision whether to include physicians' offices has already been made by many states. Some have extended CON to physicians' offices, but most have decided against such an action. We believe that this decision should continue to remain with each state which can best determine its own planning mechanisms designed to meet its own needs. The federal government should not substitute its judgments for that of the state legislatures.

We must question how the provision would apply. Would regular use for inpatients be a consideration only at the time of purchase? Or would the state be free to examine the patterns of use at anytime? What would be considered "regular" use?

The language of this provision is vague and too much subject to inappropriate definition in regulations. Lack of clarity such as this permeates PL 93-641 and has contributed to many of the problems experienced during its implementation. More vague statutory language is not needed in this Act.

We also point out that the evidence supporting the notion that certificate-of-need results in significant cost savings is not complete. That is why our amendments call for a thorough study of the certificate-of-need process to determine its efficacy. Until the study is made and such evidence is compiled, consideration of any extension of certificate-of-need would be inappropriate.

We would also offer an amendment that would make certificate-of-need for institutional services a state option. Far better, we believe, than any coercive force by the federal government, would be a system that permits the state to elect whether or not to enact a certificate-of-need law. Permitting states to seek alternate mechanisms could lead to other, very effective planning tools. However, under the restrictions of current law, such experimentation is precluded and we may never know if better solutions await discovery.

We also note that S. 544 would redefine the phrase "institutional health services" so as to include "health services provided through health care facilities as defined in regulations of the Secretary including, but not limited to, private and public hospitals, rehabilitation facilities and nursing homes" (emphasis added).

This definition is so broad that, depending solely upon his definition of "health care facilities," the Secretary might seek to assume authority to include virtually any service. Experience has shown that the Secretary will seek to define terms in the broadest sense possible. Therefore, the proposed definition, we believe, might be used as a basis by HEM to include services in physicians' offices. Clarification should be made in this language to preclude such a result.

#### Conversion of Health Facilities

S. 544 amends Title XVI of the Public Health Service Act (Health Resources Development) to establish a voluntary program for the discontinuance or conversion of unneeded health services or facilities. Federal funds would be provided as an incentive for such actions.

We are pleased that the provisions for discontinuance or conversion in S. 544 would be voluntary because we believe that a mandatory program would not work. We believe that economic incentives in a voluntary program can be an effective means of encouraging the elimination of services or facilities that may be out-moded, duplicative or unnecessary. It is far better that closure or elimination of services be initiated voluntarily at the local level.

Under the bill, each application by an institution for the conversion funds would be reviewed by the local HSA and the state agency. This recommendation would be forwarded to the Secretary who would have the final decision.

We recognize that decisions on expenditures of federal funds must ultimately be made by federal officials, but we are pleased to see that there are opportunities for the local community to have a say in the decision. This encourages local responsibility and initiative in the planning process.

Despite our enthusiasm for this proposal, we do wonder if it would not be better to initiate this program on a limited basis first in order to determine its effectiveness before a nationwide effort is undertaken. A demonstration program would be the best way to test this proposal and to insure that it is functioning well before large amounts of federal funds are committed.

#### Certificate-of-Need for Health Maintenance Organizations

S. 544 proposes a number of changes to certificate-of-need as it affects HMOs. The first change would limit CON to HMO hospitals and purchases of major medical equipment. The initial establishment of HMOs would no longer be covered



by CON. This change puts HMOs on a par with other forms of group medical practice which are not covered by CON under the Act. We believe that this change is proper. As can be seen from our attached amendment, we also support equalizing the CON treatment of HMOs.

However, S. 544 goes much further than just giving HMOs equal treatment. Other provisions would spell out the standards a state agency must use in evaluating an HMO's CON application. The result of these special criteria will be that a state agency will not be able to evaluate an HMO's application according to standards of community need.

If implemented, these proposals will essentially exempt federally qualified HMOs from the planning process. (It is interesting to note that HMOs that are not federally qualified are not covered by these proposals.) The American Medical Association believes that such a change undermines the concept of local health planning based on community needs.

The AMA believes that HMOs are an important part of a pluralistic health care delivery system and that consumers should be able to choose HMOs if they so desire. However, creating artificial standards for the review of the inpatient facilities of federally funded HMOs could be very disruptive of comprehensive health planning as it ties the hands of local agencies by allowing them to plan for only part of the health sector in their community. Exempting a major institutional resource could make it very difficult to prepare and implement effective local and state health plans. This added diminution of local control further shifts the planning power away from communities to the federal government.

A further anomaly could also be created by permitting one form of health care delivery (HMOs) to have opportunities for unlimited expansion, while other forms are restricted through CON review. Despite CON exemptions, the facilities and services of HMOs would still have to be considered along with those of other entities in meeting the national guidelines for health planning, and their un-

limited growth could distort the community health services situation thus limiting expansion of other types of facilities. This could lead to a freezing of the level and quality of medical services in non-HMO facilities. Since many people will continue to rely on non-HMO facilities for their medical care, this places a very unfair burden on them. To continue in the future to seek care at non-HMO facilities may mean getting substandard care, yet HMOs, even with all the latest in medical facilities, could not possibly absorb all these people. We believe it is wrong for HEW to force this choice on the population. It is inimical to freedom of medical choice and very destructive of a pluralistic health care delivery system. These special criteria should not be adopted.

#### Review of the Quality of Health Services

Under S. 544 planning agencies conducting mandated health systems reviews, such as CON, would be required to analyze the quality of care provided in existing facilities or through existing health services. We do not believe that this activity should be undertaken by planning agencies. Peer review mechanisms already exist to do this and are far better qualified for such tasks. Their work should not be duplicated or set aside. This provision should be deleted.

#### AMA AMENDMENTS

PL 93-641 is ripe for change and the AMA has developed several amendments to this law which we believe will go far to insure that health planning can enhance, rather than inhibit, the quality and availability of medical care.

At this time we would like to review some of our major proposals.

#### Physician Representation in the Planning Process

As we earlier stated, planning decisions should be made by those most interested in, and knowledgeable about, health services. Major sources of such knowledge are the practicing physicians in an area.

While current law makes limited provision for the representation of providers on HSA governing boards and other planning bodies, the present require-

ments tend to discourage, rather than enhance, physician participation in the planning process. Since rational planning requires a firm base, it is unreasonable and the stakes too high to discourage from involvement those most knowledgeable about the health system.

Therefore, we are proposing amendments that would require that specific percentages of practicing physicians be members of HSA governing bodies, state health coordinating councils and the national health planning council.

We are also disturbed by several provisions in S. 544 that would inhibit additional opportunities for physician participation in the health planning process. These provisions should be deleted.

One change would permit providers not currently listed in the law to be represented. Currently, physicians and other health professionals, institutional representatives, insurers, health profession schools' representatives, and allied health professions are listed. Encouraging more non-physician representation can only impair the effective input of those physicians already on the board and preclude other physicians from becoming involved in local health planning activities.

S. 544 also proposes new conflict of interest provisions for HSA members that would preclude members from participating in any matter where a member had, in the preceding three years, a financial, employment, medical staff, or competitive relationship with the institution under review. While we agree that obvious conflicts of interest should be avoided, we are concerned that this proposal is overly broad and could lead to a virtual elimination of input on many health planning decisions from both consumers and providers.

We also object to the designation of special staff to assist consumer members only. Staff should be available to serve all HSA members equally. We believe that this provision will exacerbate the consumer-provider adversary relationships that have arisen in some areas.

#### Definition of Indirect Provider

Closely associated with questions relating to proper representation of providers is the troublesome aspect created by the separate classification and definition of "indirect provider." While the law provides for "provider" representation, this requirement may be filled in large part by "indirect" providers whose characterization as a provider is very tenuous. Under PL 93-641, which sets up two classes of representation--providers and consumers--those termed "indirect provider" should more accurately be included as consumers. If this is not done or if the definition is not deleted, this will restrict the full participation of many citizens--physicians, dentists, nurses, etc.--whose participation should be encouraged. We urge adoption of our amendment at this point.

#### Mandatory HEW Standards

The proposed National Guidelines for Health Planning, published by HEW in September 1977 and finalized in 1978, are another indication of increasing federalization of the planning process. Even though the revisions are more flexible, we believe that current law still inappropriately restricts the HSA to the development of health systems plans that only reflect HEW's perceptions of health resources needs.

However, we do believe that the federal government can and should serve a useful advisory role to health planners. In this regard, it can be appropriate and helpful for HEW to issue true guidelines for health planning. However, since local initiative and flexibility are the hallmarks of a successful planning effort, federal guidelines must not preclude community-based determinations of health resource needs.

In keeping with this belief, the amendments which we have offered would allow HEW an appropriate advisory role in health planning, while precluding the preemption of local decision-making by federal officers. Adoption of these

amendments would, we believe, allay many of the fears aroused by HEW's proposed guidelines and would be a positive step toward ensuring local self-determination. We note with approval that S. 544 also contains a similar proposal.

#### Powers of the Secretary

In 1974 the AMA testified on S. 2994, the National Health Planning and Resources Development Act of 1974. Reviewing the extensive powers of the Secretary that were then proposed, we pointed out the potential concentration of power in the hands of the Secretary. Experience with the proposed guidelines tells us that the Secretary will seek, as we predicted, to maximize his control over planning the delivery of health care services at the expense of HSA's institutions and practitioners and especially at the expense of patients.

Health planning decisions must be made locally, both to be effective and acceptable. Our proposals are aimed at restoring to local communities the decision-making power in health planning, and more importantly, are specifically aimed at curbing excessive powers of the Secretary. We cannot emphasize enough the need at this time to realign the planning by circumscribing excessive federal authority as a fundamental step in insuring a rational determination of need for health resources based on community and patient needs. S. 544 also contains several amendments that would increase the influence of the governors of the various states that are similar to ours.

#### Public Hearings

Certain activities in the planning process are already subject to public scrutiny and comment, such as the development of health systems plans.

However, other actions are not subject to such review and we think they ought to be. In particular, the development of the annual implementation plan

Should be subject to public hearings on its contents. We are pleased that this Subcommittee is considering an amendment that would achieve this. We urge its adoption.

We would also urge that any changes in the HSP suggested by a statewide health coordinating council be subject to public hearing and review. Since an HSP is a locally developed product, the citizens involved in its preparation should have a reasonable opportunity to comment on any proposed changes.

#### OTHER PROVISIONS

##### Mental Health

We are pleased that S. 544 contains provisions to enhance community awareness of the needs of the mentally disabled. Unfortunately, the needs of these people are too often overlooked. Requiring inclusion of mental health needs in state and local plans can increase awareness of these problems and hopefully lead to better services for the mentally ill.

##### Rural HSAs

Another beneficial provision would increase the minimum funding for HSAs. This is very important for rural areas. Funding shortages for many rural HSAs have prevented them from doing their best to plan for needed community health services and facilities. Increased funding will enable these agencies to respond more creatively to local needs and will lessen their reliance on federally prepared planning formulas that often have no relevance to local circumstances.

##### Conclusion

There are many areas of PL 93-641 that need change before community-based health planning can become a reality. S. 544 makes some of these changes and we have attached a summary of other amendments believed necessary. We are prepared to meet with the Subcommittee to discuss the specific language of these proposals.

We believe that our amendments are fundamental to making the health planning system more responsive to the needs of each community. By being so responsive, health planning can better achieve desirable objectives.

In our statement we have sought to address certain important areas of S. 544. We have pointed out our opposition to extension of certificate-of-need to physicians' offices and to unfair advantages for HMOs. We have also pointed out our support for programs providing appropriate incentives for closures and conversions. Our primary concern on these stands is the maintenance of access of quality health care.

SUMMARY OF AMENDMENTS TO PL 93-641A. Issuance of National Health Planning Guidelines

Amendments would make clear that any national guidelines issued by the Secretary of HEW are not to be mandatory standards. Guidelines would be advisory only and HSAs would have flexibility in the design of their local plans.

Another amendment would require consultation with certain professional parties before issuing any guidelines rather than allowing interpretation by the Secretary as to when consultation would occur.

B. Definition of Provider and Health Care Facility

The current definition of "provider of health care" would be amended. The term "indirect provider" would be removed. Thus, only "direct" providers would be considered as providers.

The definition of health care facility would also be amended specifically to exclude a physician's office.

C. State Rate Review Programs

This amendment would delete federal funding authority for establishment of state rate review programs.

D. Certificate-of-Need

A basic concern with P.L. 93-641 is that certificate-of-need (CON) laws must be adopted by all states. Amendments would make CON a state option. In addition, an amendment would require a study of the effects of CON programs.

E. VA and HMO Representation

Amendments would delete required VA or HMO special representation on HSA governing bodies and SHCCs.

F. Confidentiality of Data

The provisions assuring the confidentiality of data gathered or held by HSAs are inadequate. Since material may contain sensitive patient information, it is desirable to have proper protection. Changes to the law would provide for HSA protection of confidential information.

G. Uniform Reporting

The Secretary is presently authorized under P.L. 93-641 to establish uniform cost accounting and reporting systems. A uniform system for rate calculation, and a system for classification of health services



institutions are also required. Because of duplication with similar authorizations in recently enacted P.L. 95-142, this authorization would be deleted in P.L. 93-641.

#### H. Review of Grant Applications

Under current law, HSAs would review and approve or disapprove applications for funds under a number of grant programs. The provision would be amended to permit HSAs and SHPDAs only to review and comment on such applications; they would not have the power to approve or disapprove. Since the Secretary of HEW in any event has final approval of an application, the amendment would assist primarily in hastening the review process by establishing specific time limits for review.

#### I. Payments to HSAs

Under the current law, HSAs receive their funding almost completely from the federal government, thus insuring a tight rein on their activities by HEW. Sharing the costs between the federal and state governments (or other non-federal sources) would lessen HEW's control and give to the states a greater voice and interest in planning activities.

An amendment would limit the federal share of HSA costs to 75 percent. Maximum flexibility would be permitted in making up the other 25 percent. In addition, a total federal dollar limitation (based on a per capita calculation) is imposed on the HSA.

Another amendment would delete the Area Health Services Development Funds which provide for development of projects by the HSA -- an unnecessary and undesirable function by the HSA.

#### J. Authority of the Secretary of HEW

The powers of the Secretary in the planning process are such that he can exert great control over HSAs, SHPDAs and SHCCs.

A series of amendments are intended to lessen that authority. One amendment converts the present "National Health Priorities" into items for "consideration" rather than "priority consideration".

Another amendment removes the mandated number of HSA staff and allows for contracts with consultants.

A third amendment allows approval of a state administrative program "substantially" meeting required conditions rather than referring absolute compliance.

#### K. Hearing Requirements

One amendment would subject an HSA's annual implementation plan to hearing and comment. A second amendment requires that a SHCC, before revising an HSA's plan, have a public hearing on the revision.

#### L. Designation of Health Service Areas

This series of amendments affects the designation procedures for health service areas. One prohibits interstate HSAs unless the Governors of all the states involved agree to an interstate designation.

Two other amendments give Governors the final approval over designation of HSA boundaries and provide a mechanism for revision of boundaries.

#### H. Federal Facilities

An amendment would subject federal facilities to the same considerations of certificate-of-need as may apply to non-federal facilities.

#### N. Representation of Physicians on Planning Bodies

Amendments would establish a required representation for practicing physicians on the National Council for Health Planning and Development (at least 4), on State Health Coordinating Councils (SHCCs) and on HSA governing bodies (at least 40% of the providers on each body).

#### O. Penalty for State Failure to Designate State Health Planning and Development Agency (SHPDA)

Presently, any state that fails to enter into an agreement with the Secretary to designate a SHPDA will lose all Public Health Service Act funds within the state as well as funds under the Community Mental Health Centers Act and the Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act.

The AMA recommends that the penalty resulting in the loss of all PHS funds be deleted. Any penalty should relate to a loss of planning funds only.

#### P. Information Developed by Centers for Health Planning

An amendment would require Centers for Health Planning to make materials developed available to the general public.

#### Q. Antitrust Exemption

A new section would be added to exempt actions taken in meeting the requirements of the Act from federal antitrust laws.

#### R. Approval of State Health Plan by Governor

An amendment would empower the Governor of each state to approve a state health plan or any revisions in such a plan.

#### S. Technology Review

Under the current planning law the National Council on Health Planning and Development has authority to review health technology. This section duplicates other authorities and should be deleted.

#### T. Appeal for CON Decisions

The Act currently does not provide an appeals mechanism when a Health Systems Agency and the State Health Planning and Development Agency arrive at different conclusions on a Certificate-of-Need application. An amendment would specify an appeals process, using the Statewide Health Coordinating Council as the reviewing body. In order to enable the SHCC to more objectively perform this function, and its other duties, an amendment would separate staffing for the SHCC. The Act presently allows the SHCC and SHPDA to utilize a joint staff, which may result in a conflict of interest.

#### U. Certificate-of-Need for the Initial Establishment of HMOs

The definition of "institutional health services" now in the planning law includes health maintenance organizations. Thus a CON must be obtained for the initial establishment of HMOs.

Proponents of HMOs have argued that this requirement discriminates against HMOs and inhibits reasonable competition in the health care industry. It has been suggested that the establishment of an HMO is similar to the establishment of a fee-for-service group practice, the main difference being the payment mechanisms for each type of practice. Since CON is not required under federal law for the establishment of a group practice, it is argued that it should not be required for the establishment of an HMO.

The AMA believes that CON should continue to relate to inpatient facilities of HMOs, but not to HMOs insofar as they are similar to group practices and relate to establishment. Thus, as a general rule CON would not be required for the initial establishment of an HMO, but it would be required of the HMO as to inpatient facilities. This would be consistent with the law's application to hospital or other inpatient facilities.

#### V. Special Preferences for HMOs

Under the current law, HSAs and SHPDAs have to consider the "special needs and circumstances" of HMOs in making CON reviews, appropriateness review, and when reviewing grant applications (1532(c)(8)). As interpreted by HEW in currently proposed regulations, this provision would make it extremely difficult for planning agencies to conduct review of an HMO in a balanced fashion.

The proposed rules would put HMOs at a great advantage vis-a-vis other health care facilities. To restore a more appropriate competitive balance, this preference should be deleted.

## Abbreviations:

HSA	-	Health Systems Agency
SHCC	-	State Health Coordinating Council
SHPDA	-	State Health Planning and Development Agency
CON	-	Certificate-of-Need
PHS	-	Public Health Service



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March 13, 1979

Hon. Edward M. Kennedy, Chairman  
Subcommittee on Health and Scientific  
Research  
Senate Labor and Human Resources Committee  
Washington, D.C. 20510

Dear Mr. Chairman:

Attached you will find three (3) copies of our prepared statement on amending P.L. 93-641, the National Health Planning and Resources Development Act.

We would be most appreciative if you would consider our arguments and assure that the statement is included in the permanent hearing record.

Thank you in advance for your assistance in this regard.

Sincerely,

C. Robert Benedict  
Director



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AMERICAN OSTEOPATHIC HOSPITAL ASSOCIATION  
Statement Presented to the Senate Labor and  
Human Resources Committee

Subcommittee on Health

Views on Amending P.L. 93-641

March 16, 1979

This statement is presented by Michael F. Doody, President, of the American Osteopathic Hospital Association, 930 Busse Highway, Park Ridge, Illinois 60068.

The AOHA maintains its Headquarters in Illinois, with an office in Washington, D.C., and represents the 208 osteopathic hospitals which are located in 28 states. These institutions serve as the primary institutional care facilities for those patients (individual consumers) who choose to receive their health care from one of the approximately 15,000 practicing osteopathic physicians in the country.

INTRODUCTION

The primary goal of sound health planning is to assure that high quality services are available, accessible and viable to the patient population. Public Law 93-631, the National Health Planning and Resources Development Act, requires each state to establish a certificate of need program which would set forth criteria for use by a state agency in evalua-

ting all new institutional health services proposed to be developed or offered within the state.

Osteopathic hospitals strongly support the basic concepts of sound community planning by providers of health care, consumers and public agencies that will provide for community health needs in a responsible and effective manner. Section 1532 (c) of P.L. 93-641 sets forth minimum criteria the states must adopt in their certificate of need programs. These criteria do not, however, include language to assure that individual consumers/patients will be guaranteed their right to select the provider of their choice. We are not suggesting a change in the law with regard to the necessity of applying for and receiving a certificate of need. This can be accomplished by an amendment to Section 1532 (c) which would include language mandating consideration of the availability of both osteopathic and non-osteopathic facilities and services within a community.

The AOHA is very concerned with the distinct identification of osteopathic facilities and services. It is important that any inventory of institutional health services, and in any comment on the appropriateness of health services, that osteopathic health services be identified as being osteopathic and not casually included in a single number or description of similar health services. It is important that any cataloguing of institutional health services recognize the fact that there are certain diagnostic and therapeutic health services unique to the osteopathic hospital.

#### What is an Osteopathic Hospital?

Osteopathic hospitals are fully licensed, accredited and approved

institutions that provide a full range of medical services to their communities. They comprise an important and significant segment of the total health care industry.

Today the 208 osteopathic hospitals located in 28 states provide nearly 25,000 beds for the treatment of the sick and injured.

An estimated 800,000+ patients are admitted to osteopathic hospitals each year, resulting in some 6.3 million patient days of care. In addition, the outpatient departments of osteopathic hospitals accept more than three million patients each year for emergency and other ambulatory care.

The care of patients in osteopathic hospitals is an extension of the care available in the offices of the osteopathic physician (D.O.). An osteopathic hospital is staffed by a team of osteopathic physicians. There are many forms of discomfort and disease which are dealt with daily in all hospitals, in which osteopathic concepts introduce a distinction between non-osteopathic and osteopathic approaches.

The osteopathic physician has an additional dimension to his training and practice which is not taught in medical schools giving M.D. degrees. The D.O. recognizes that the musculoskeletal system (the muscles, bones and joints) make up over 60 percent of the total body mass. He also recognizes that all body systems, including the musculoskeletal system, are interdependent, and a disturbance in one causes altered function in other systems of the body.



This interrelationship of body systems is effected through the nervous and circulatory systems. The emphasis on the relationship between body structure and organic functioning gives a broader base for the treatment of the patient as a unit.

These concepts require a thorough understanding of anatomy and the development of special skills in recognizing (diagnosing) and correcting (treating) structural problems through manipulative therapy. The D.O. uses structural diagnosis and manipulative therapy along with all of the other more traditional forms of diagnosis and treatment to care effectively for patients and to relieve their distress.

Osteopathic medicine offers something more--not something else.

Osteopathic medicine is a second school of medicine in which the vast majority of the practicing osteopathic physicians are general practitioners, many of whom serve in rural and semi-rural areas. According to recent data, more than 65% of all the D.O.'s in the nation are general practitioners. Similar statistics show that only 15-20% of the M.D.'s in the U.S. are engaged in general practice. A more significant figure, however, is that of the total general practitioners in the U.S., more than 17% are D.O.'s. This is in a profession which currently comprises only slightly more than 4% of all practicing physicians nationwide.

The federal government, state governments, and private and public health agencies have recognized osteopathic medicine as a separate but equal branch of American health care. As a result, osteopathic physicians have the same rights and same professional obligations as non-osteopathic (M.D.) physicians.

The American Osteopathic Hospital Association maintains that the osteopathic profession and its continuing emphasis on general practice rather than medical specialization best serves the health care needs of the American public.

#### The Postdoctoral Education of Osteopathic Physicians

The postdoctoral education of these professional physicians is dependent upon the continued viability of osteopathic hospitals--more than 40% of which are involved in the post-graduate education of osteopathic physicians.

The accrediting agency for all osteopathic education is the American Osteopathic Association (AOA). The AOA has been so designated by the National Commission on Accreditation of the Office of Education, Department of Health, Education and Welfare. In both federal and state legislation, as well as in the Medicare and Medicaid statutes, the AOA is repeatedly recognized as the accrediting body for all osteopathic education, and the osteopathic profession is recognized as a second school of medicine, separate and distinct from the non-osteopathic school.

The AOA can only approve programs in those AOA accredited hospitals offering distinct osteopathic training based on the unique osteopathic philosophy. These institutions are subject to stringent inspection by the AOA and must meet their requirements to maintain accredited training programs. This training results in the production of a physician who can treat families, rather than a physician who restricts his practice to one specialty.

Millions of Americans have freely chosen to seek their care from osteopathic physicians and hospitals. The shortage of family practitioners in this country has caused the establishment of new colleges of osteopathic medicine, which are supported by the community in which they are located and in many cases by state and local funds.

Today there are 14 colleges of osteopathic medicine, 9 of which graduated students in 1978. The remaining five colleges will be graduating their first classes between 1980 and 1982. The number of projected graduates from the colleges over the next four years will increase from 965 in 1979 to more than 1200 in 1982.

Today, more than 85 osteopathic hospitals (more than 40% of the total number) are approved by the AOA for intern training. These hospitals currently have 974 approved intern training positions. Taking into consideration that a number of graduates will enter federal service, there were sufficient positions in osteopathic hospitals for graduates in 1978. However, in the coming years, the increasing number of graduates will place a critical burden on our institutions unless provision can be made to expand the teaching programs in qualified hospitals.

Recent statistics compiled by our Association show that nearly half of the 208 osteopathic hospitals across the country are located in communities with populations of 50,000 or less. More than 30% of all osteopathic hospitals are located in communities of 20,000 or less. These figures indicate that our hospitals provide care to many smaller communities and further points to the necessity of the continuing viability of these institutions.

It is not difficult to see the very important relationship between the concept of certificate of need and the ability of the osteopathic profession to continue to educate physicians who will engage in general practice in the the delivery of primary care to millions of Americans, especially in geographic areas of need.

#### Discrimination

It is feared that without provision for consideration of osteopathic facilities and services, osteopathic hospitals will not be allowed orderly growth and expansion where the need is justified. There is little doubt that there has been discrimination over the years against osteopathic physicians and hospitals in their efforts to provide needed health services to the communities in which they are located. A list of specific hospitals which have experienced discriminatory actions include: Osteopathic Hospitals of Detroit, Inc. - East Unit (formerly Art Centre Hospital Osteopathic) in Detroit, Michigan; Tucson General Hospital in Tucson, Arizona; Pontiac Osteopathic Hospital in Pontiac, Michigan; Sandusky Memorial Osteopathic Hospital in Sandusky, Ohio; Grand Rapids Osteopathic Hospital in Grand Rapids, Michigan; Flint Osteopathic Hospital in Flint, Michigan; and Des Moines General Hospital (Osteopathic) in Des Moines, Iowa.

In Arizona on March 31, 1976, the Superior Court in Pima County ruled in Tuscon Genral Hospital vs. James I. Schamadan, M.D. that "to construe 'public need' to mean the public in general as opposed to a segment of the population which desires or prefers services by an osteopathic physician is to construe it too narrowly. If a considerable portion of the public desires the services of an osteopathic physician, it is the court's

opinion that the 'public need' requirement of the statute is satisfied." The decision went on to state that a certificate of need, previously denied Tucson General Hospital, an osteopathic institution, must be granted.

On August 5, 1976 Rocky Mountain Hospital in Denver, Colorado received authorization for construction of a renovated and enlarged delivery area and for the remodeling and expansion of the hospital's surgical suite from the Colorado Health Facilities Council. In a precedent setting decision for the state, the Council granted approval for a certificate of need on the basis that the hospital is an osteopathic teaching institution. The construction was necessary to maintain AOA accreditation as well as approval for intern/residency training.

Because of this past history, and in recognition of the unique and important role played by osteopathic hospitals, several state legislatures have given consideration to language that specifically requires separate consideration and evaluation of osteopathic hospitals in the certificate of need process. Thus far, the states of Oklahoma, Rhode Island, Florida, Iowa, Maine and Michigan have enacted legislation along these lines. In Ohio, the same effect was achieved through the regulatory process.

Attached to this testimony, you will find citations of the language currently in force in these states.

Also attached, as Appendix B, you will find documentation of six representative cases of discrimination against osteopathic hospitals and physicians which serve to illustrate and reinforce the need for the type of language we are seeking. The first three examples you will find are from

Michigan, Ohio and Iowa. They point out the type of discrimination which can be and has been encountered with local health planning agencies. The fourth example is from Art Centre Hospital Osteopathic in Detroit and it delineates the kind of discrimination which is occasionally encountered with the state planning agencies. The fifth example is a case in which a physician encountered discrimination in his attempts to obtain privileges at a nearby non-osteopathic facility. The sixth illustrates the concerns expressed by a very conscientious governing body of an osteopathic hospital regarding an arbitrary HSA decision which was only marginally passed and which could become policy.

#### Previous Federal Efforts

It is most important to note at this point that this Association and the osteopathic profession waged a lengthy and unsuccessful campaign to seek inclusion of appropriate language in the regulations issued by the Department of Health, Education and Welfare to implement the certificate of need program. That effort failed, not because HEW believed our cause was invalid, but because the language in Section 1532 (c) of P.L. 93-641 does not provide sufficient flexibility to allow for such consideration in the regulations. In the commentary on the proposal of the osteopathic profession, then Secretary of HEW David Mathews called our concern largely "anticipatory". The examples cited previously in this testimony prove this not to be the case and many of the letters of support for our proposal from Members of Congress add further evidence that the concern is a valid one.

A number of Senators and Representative wrote to then Assistant Secretary for Health, Theodore Cooper, M.D., in support for our proposal. We

believe citations from two of those letters are very pertinent to this discussion. The first is from a letter written by Senator Thomas F. Eagleton (D-Missouri) which said in part:

"It has been brought to my attention that the proposed regulations may, in practice have the effect of discriminating against osteopathic hospitals. For this reason, I believe that the proposed regulations should be revised along the lines suggested by the American Osteopathic Hospital Association.

"Perhaps more than any other state, Missouri depends upon osteopathic physicians to provide health care to its citizens. We are fortunate to have two fine schools of osteopathy in Kirksville and Kansas City, Missouri, whose graduates often locate within the state. Osteopathic physicians are of particular value in Missouri because most of them are engaged in delivering primary health care and many are located in rural areas that would otherwise be unserved or underserved."

The second citation is from a letter by then Senator William D. Hathaway (D-Maine) to Dr. Cooper:

"In my state of Maine, for example, osteopaths make up a substantial portion of the pool of primary practitioners. In many places osteopaths are denied hospital privileges in allopathic hospitals. Given the particular needs of osteopathic physicians, as well as other groups whose service area should be developed separately, I would urge that the final regulations reflect the consideration that must be given to these provider groups and their patients so they may exercise their freedom of choice consistent with the availability of resources and the intent of this Act."

Finally, there were thousands of comments received by HEW from the osteopathic profession and their patients in response to the proposed rules implementing the certificate of need program. A few citations from some of those comments further support our arguments:

"We believe it to be a constitutional right of Americans to select providers of their choice and that government has an obligation not to legislate against that precious freedom. We can find no substantive argument that makes our appeal an unreasonable one. A growing number of states, including our own, have passed or are

considering legislation that does recognize the need to avoid complete monopoly, and we do not see how you can do less.

"Maine is a state that has long struggled to create a medical school as a means of providing primary care physicians to its citizens. The osteopathic profession has realized this need and is well on the way to filling that need by the creation of the New England School of Osteopathic Medicine to be located at Biddeford, Maine, at the campus of St. Francis College.

"It is imperative that the future of this school not be jeopardized by rules that fail to provide for the facilities and services necessary to support such an effort. Similarly, physicians presently in practice must be free to continue providing for their patients in an environment that recognizes their distinctive approach to patient care."

(April 15, 1976, signed by 14 D.O.'s, James A. Taylor Osteopathic Hospital, Bangor, Maine.)

"In summary, the law places all facilities in the same barrel for planning purposes, but Osteopathic (D.O.) and Allopathic (M.D.) hospitals often serve entirely different publics. Thus, there is a good possibility that justified osteopathic needs could be disapproved because of an excess of allopathic facilities in the Community or the reverse situation could also exist.

"As you may be aware, we were able to solve this problem in Ohio by amending the Ohio Sanitary Code by including in the State regulations a sentence or two which allows the planning agency to consider this special problem."

(April 16, 1979, Richard L. Sims, Administrator, Doctors Hospital, Columbus, Ohio.)

"The purpose of this letter is to impress upon you our belief that additional language in these proposed regulations is crucial, in order to protect the rights of osteopathic hospitals, osteopathic physicians and their patients. As you probably are aware, medical staff privileges at other hospitals in Texas are not readily available to osteopathic physicians. Therefore, a substantial number of our population look to osteopathic hospitals to provide the care they need for themselves and their families. It is important to note that allopathic hospitals are not generally accessible to those patients who elect to use osteopathic physicians. As a result we do not feel it should be left to the discretion of the States whether or not to include separate consideration for osteopathic facilities and services."

(May 3, 1976, Claude G. Rainey, Executive Vice President, Fort Worth Osteopathic Hospital, Fort Worth, Texas.)



"Perhaps your understanding of why I became associated with the Osteopathic Hospital would help you to understand why I believe there should be equal, but separate consideration in the certificate-of-need matter. Over 25 years ago my daughter was deformed from her knees down. My wife and I went to several medical doctors only to hear from each one that the problem could be corrected by fracturing each leg in three places and wearing casts from 6 months up. We finally visited an Osteopathic doctor who told us that it might be necessary to do as the medical doctor had told us, but that treatment could be done anytime until 6 years of age. He would like to try osteopathic treatments first. For the next 6 or 8 months my wife and I did the treatment on the legs exactly as we had been taught. We also bought the built up shoes which he designed and made sure she wore them during the treatment. Anyway, in about two years she had beautifully straight legs and has never had any leg problems since."

(April 28, 1976, H.C. Bevelhymmer, Wichita, Kansas.)

#### CONCLUSION

The American Osteopathic Hospital Association supports sound community health planning; we do not wish to be exempt from the planning law and we are not suggesting a change in the law with regard to the necessity of applying for and receiving a certificate of need. We are not seeking a license to plan in a vacuum, oblivious to the realities which surround us. There is ample evidence that the osteopathic profession and osteopathic hospitals fulfill a vital role in today's health care delivery system and, if allowed to function and plan on the same basis as all other hospitals, unfettered by the restraints of discriminatory and/or politically influenced actions on the part of local and state agencies, the ultimate beneficiary will be the communities we serve.

Therefore, we suggest the following language as an amendment to P.L. 93-641 which would provide for appropriate consideration of osteopathic facilities and services in all applications for certificates of need:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 1532 (c) (3) of Public Law 93-641 is amended by adding the following: "When an application is made for a certificate of need to construct, expand, modernize, acquire capital equipment or add services by an osteopathic or allopathic facility, the need for that construction, expansion, modernization, acquisition of capital equipment, or addition of services shall be considered on the basis of need and availability in the community for services and facilities for osteopathic and allopathic physicians and their patients. The Health Systems Agency and State Agency shall consider the application for a certificate of need in terms of its impact on preserving existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship and residency training levels. Nothing in this criteria shall be construed to dictate a departure from good health planning principles or to mandate unnecessary duplication of services or facilities."

The consumer, the patient, who chooses to seek health care from an osteopathic physician and hospital must be given appropriately equal opportunities under any and all certificate of need laws and regulations. Osteopathic hospitals and physicians must be allowed to continue to serve their communities as they have for the past 100 years.

The American Osteopathic Hospital Association appreciates the opportunity to testify on this most critical matter and strongly urges this Subcommittee to favorably consider the language we are proposing today. We stand ready to answer any and all questions which you might have. Thank you.

APPENDIX A

## CITATIONS OF OSTEOPATHIC CERTIFICATE OF NEED

## LANGUAGE CURRENTLY IN FORCE

1. Ohio--HE-8-17 (C) Criteria to be Applied in the Review  
of Proposals (Effective 1/19/76)-----
2. Florida--Title 27, Section 381.494 (2) Capital Expendi-  
tures for Health Care Facilities (1972)-----
3. Rhode Island--Chapter 23-16, Section 12 (1974)-----
4. Oklahoma--Title 63, Article 7 (1975)-----
5. Iowa--House File 354 (Citation not yet available) (1977)-----
6. Michigan-- Part 221, Section 22131 (1) (n)-----
7. Maine--Section 1.22MRSA c. 103, Section 309,  
Paragraph J.-----

OHIO

He-8-17 (C) Criteria to be Applied in the Review of Proposals (Effective 1/19/76).

To protect the freedom of patient choice, the needs of the patients of both osteopathic and allopathic physicians shall be considered. In such instances, those facilities and services shall be authorized where there is demonstrated need for osteopathic or allopathic facilities and services.

FLORIDA

Title 27, Section 381.494 (2) Capital Expenditures for Health Care Facilities (1972).

Certificate of need.--When an application is made for a certificate of need to construct or to expand an osteopathic facility, the need for such facility shall be determined on the basis of the need and availability in the community for osteopathic services and facilities.

RHODE ISLAND

Chapter 23-16, Section 12 (1974).

When an application is made for a certificate of need to construct or to expand an osteopathic facility the need for such facility shall be determined on the need and availability in the community for osteopathic services and facilities.

OKLAHOMA

Title 63, Article 7 (1975).

"Promptly upon receipt of any such application, the Commission shall cause a thorough investigation to be made of the need of the proposed services. The investigation shall include..."

(c) the availability of both allopathic and osteopathic facilities and services to protect the freedom of patient choice in the locality..."

IOWA

House File 354 (Citation Not Yet Available) (1977).

Sec. 4. CRITERIA FOR EVALUATION OF APPLICATIONS.

1. In determining whether a certificate of need shall be issued, the department and council shall consider the following:

j. The appropriate and nondiscriminatory utilization of existing and available health care providers. Where both allopathic and osteopathic institutional health services exist, each application shall be considered in light of the availability and utilization of both allopathic and osteopathic facilities and services in order to protect the freedom of choice of consumers and health care providers.

MICHIGAN

Part 221, Section 22131 (1) (n).

On making determinations and conducting reviews for certificates of need, the department and a health systems agency shall apply at least the following criteria:

(n) When an application is made for a certificate of need to construct or expand an osteopathic or allopathic facility, consider the need for that facility on the basis of the need and availability in the community for services and facilities for osteopathic and allopathic physicians, other licensed health care professionals, and their patients and the impact of the application for a certificate of need on existing and proposed institutional training programs for doctors of medicine and osteopathy and other licensed health care professionals at the student, internship, and residency training level. This subdivision shall not be construed to dictate a departure from good health planning principles or to mandate unnecessary duplication of services or facilities.

MAINE

Chapter 103, Section 309, Paragraph 2J:

2. Criteria for certificate of need...

J. The importance of recognizing the public's choice of allopathic or osteopathic health services by considering the unique needs and circumstances of providers of allopathic and osteopathic health care;

APPENDIX BDOCUMENTATION OF SPECIFIC CASES OF DISCRIMINATION AGAINST  
OSTEOPATHIC HOSPITALS AND PHYSICIANS

1. Michigan--Flint Osteopathic Hospital-----
2. Ohio--Sandusky Memorial Osteopathic Hospital-----
3. Iowa--Des Moines General Hospital (Osteopathic)-----
4. Michigan--Art Centre Hospital-----
5. Colorado--Lee Clinic-----
6. Michigan-- The Grand Rapids Osteopathic Hospital-----



## Flint Osteopathic Hospital

A NONPROFIT CORPORATION / 2521 Beecher Road / Flint, Michigan 48902 / Phone 762-4000

January 17, 1978

C. Robert Benedict  
Director  
American Osteopathic Hospital Association  
603 Pennsylvania Ave. S.E.  
Washington, D.C. 20003

W. DALE FERGUSON  
President

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General Motors Parts Division

EDWIN E. LUKE  
A.G. Edwards & Sons, INC.

Dear Bob:

Approximately two years ago Flint Osteopathic Hospital submitted a letter of intent for certificate of need to install a CT Brain Scanner. I will illustrate for you a very significant problem that osteopathic hospitals have when it comes to certificate of need. That problem is directly and indirectly, the local HSA's and the allopathic community create very high standards when an osteopathic hospital is involved.

In the instance of our application for the CT Scanner entirely new criteria were developed and demanded by FOH. All of these were met, yet repeatedly throughout the process we were attacked, harrassed, and abused as an osteopathic hospital and profession whether we were qualified to have access to a CT Scanner. FOH went through a process of three public hearings.

1. The first hearing, the allopathic physicians and hospital claimed there was no need whatsoever for a CT Scanner.
2. The second hearing, they indicated there was a need for a CT Scanner but not in an osteopathic hospital.
3. The third hearing, the allopathic community indicated there should be a CT Scanner in every hospital including the osteopathic hospital.
4. The recommendation of the HSA staff was the first CT Scanner not be in an osteopathic hospital, even though eighty percent of the scans would be done on an outpatient basis.
5. No recognition was given to the osteopathic physician who was qualified to interpret the CT Scans. The health facility committee of the local HSA recommended that FOH get the scanner. The Board of Trustees of HSA agreed that FOH

receive the scanner. The application and endorsement then went to the State Department of Public Health. FOH was repeatedly pressured to delay the certificate of need process so that other hospital projects could be considered at the same time. We refused to step out of the guideline boundries of the certificate of need deadlines. We finally receive our certificate of need after undue delay and harassment.

The verbal abuse that the profession and the hospital received in the community was tremendous. This was done at public hearings and in many different directions. Our trustees were repeatedly attacked at social gatherings and by other means. The profession was attacked repeatedly by the allopathic community. This still occurs today in many social settings in which I, trustees and fellow osteopathic physicians are criticized because FOH has a CT Scanner.

Since operational the CT Scanner has done a tremendous service for the community but never has anyone given us recognition for this service.

It is obvious that when an osteopathic hospital requests certificate of need, never is the unique role its service to the community ever recognized and accepted by the allopathic community. We receive a tremendous amount of lip service in a private manner, but never publicly.

I am more convinced than ever, that the osteopathic hospitals need a separate certificate of need. Here in our community, Flint Osteopathic Hospital runs 91% occupancy. We are a 401-bed hospital. We deliver more babies than any other institution in the city. We estimate our growth is 50 osteopathic physicians added to our medical staff in the next three to five years. With this projected increase, we need additional acute care beds. Yet we are well aware that when we do proceed through the certificate of need process, we will be severely hampered because the allopathic community will attack the osteopathic profession. The allopathic profession does not understand and want to accept the distinct mode of practice and market penetration that the osteopathic profession has made in community in which they service.

FOH is the only hospital in this community that has had any significant increase in its service base in the last ten years. Our potential for the future is as great as it has been for the last ten. Yet we will be hampered, harrassed, and abused. FOH will definitely have ten times harder time proving our case because we are an osteopathic hospital. Not because we provide better care and service, but strictly because we are an osteopathic hospital.



I once heard a leading allopathic physician in this town, say that we try harder but what he failed to recognize is that we also are more successful and the community has responded to this acceptance of the profession. Yet, when it becomes evident of our needs, we have to withstand tremendous direct and indirect pressures to stay within limited boundaries. This is completely against the will of the people and only serves the allopathic profession.

Very truly yours,

*W. Dale Ferguson*

W. Dale Ferguson,  
President

WDF:bc

# Sandusky Deaconess Hospital

An Osteopathic Institution

2020 Hayes Avenue

Sandusky, Ohio 44870

Phone (419) 626-2342

September 8, 1976

Michael F. Doody, President  
 American Osteopathic Hospital Association  
 1211 Connecticut Avenue, N. W.  
 Suite 212  
 Washington, D.C. 20036

Dear Mr. Doody:

Enclosed is a copy of a newsletter published by the "b" agency in our area during the time we were applying for our expansion program.

Several months after this newsletter appeared Dr. Cashman was replaced by Dr. Ackerman as Director of Health. Dr. Ackerman rescinded the "Cashman decision" and gave our project total approval. This decision was in turn upheld by HEW.

Also enclosed is my response to the newsletter to the President of the "b" agency.

Our main concern, even now, is the complete lack of recognition of the special needs of Osteopathic Hospitals.

Our Board of Trustees and our Medical Staff are committed to maintaining an Osteopathic Hospital in our community. And as a result of more Osteopathic Physicians joining our staff we find it necessary to expand we feel we should be allowed to expand regardless of the occupancy levels of non-osteopathic hospitals in our community.

Furthermore we find it difficult to believe that our "b" agency will not consider the fact that we are an osteopathic institution.

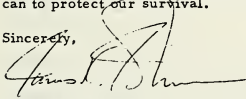
Michael F. Doody, President  
Page-2-

September 8, 1976

I hope that this information helps you and I hope you are able to bring about and end to this kind of discrimination.

I might add that the federal government should consider osteopathic hospitals as an "endangered species" and therefore should do all it can to protect our survival.

Sincerely,

A handwritten signature in dark ink, appearing to read "James K. Johnson", written over a large, stylized "S" or "J" mark.

James K. Johnson  
Administrator

JKJ:em

Enc-2

# Sandusky Memorial Hospital

Al. Hospital Institution

2020 Hayes Avenue

Sandusky, Ohio 44870

Phone (419) 626-2342

January 13, 1975

Kenneth B. Krarkoff, D. D. S.  
 President, Board of Trustees  
 225 Allen at W. Wayne Street  
 Maumee, Ohio 43537

Dear Dr. Krakoff:

I have received a copy of the HPANWO newsletter. In particular your letter to Dr. Cashman I find in extremely bad taste. In addition as the Administrator of Sandusky Memorial Hospital and as a member of the Erie County Health Planning Council, I find it offensive.

Throughout the process of gaining approval for our expansion program we have strictly adhered to the guidelines established by Section 1122 of the Social Security Act and as administered by the Designated Planning Agency of the State of Ohio. The HPANWO is a part of this process. The Areawide Facilities and Service Committee, a committee of your Board, after a thorough review approved our expansion program.

The statement you made in your letter to Dr. Cashman, "I will find it very difficult in the future to ask our committees and Board to spend the time and energy needed to complete an exhaustive review which apparently is not considered" is difficult to understand. You feel perfectly free to criticize Dr. Cashman's decision and yet your Board readily overturned the decision of the committee you charged with completing an exhaustive review of our expansion program.

I have no quarrel with the decision of the Board of Trustees of HPANWO to deny approval of our expansion program. However, just as the Board of the HPANWO is the final decision-making authority in Northwest Ohio on projects like ours so is the Designated Planning Agency the final decision-making authority in the State of Ohio. Through its Director, Dr. Cashman, the Designated Planning Agency of the State of Ohio has granted approval for funding our expansion program. At this point

Kenneth B. Krakoff, D.D.S. -2-

January 13, 1975

I wonder why "the HPANWO will continue to vigorously oppose this project". It would appear to me that your organization has had input into the decision-making process regarding our expansion program and statements like "concession to political pressure", and "to expose themselves to the pressures and potential retaliations of disgruntled applicants" not only seem out of order but may have legal implications if those statements in any way hinder or damage the ultimate approval of our expansion program.

Several other statements in the article allude to the fact that the HPANWO is not against the expansion of Osteopathic Hospitals or is the HPANWO against the Osteopathic profession. Based on your actions and the article in your organization's newsletter I find this hard to believe. The article in your organization's newsletter states that you recognize the uniqueness of our institution and yet you never considered this uniqueness when your Board denied approval of our project. If your organization's recognition of our uniqueness was adopted nationwide it would not only mean the eventual elimination of Osteopathic Hospitals but the ultimate elimination of Osteopathic Physicians as we know them today. I am thankful that other states have adopted different policies than the State of Ohio. They have developed "certificate of need legislation" that provides for the expansion of osteopathic hospitals based on the need for individual osteopathic hospitals to expand.

As for the osteopathic physicians joining the staffs of the two medical hospitals in Sandusky, I suggest that first you get the staffs of the two medical hospitals together.

I agree with the statement that one emergency room fully staffed and equipped would be superior to three. In a similar fashion it would appear that two or three strategically placed emergency rooms in the Toledo area would be superior to nine.

However, if your rationale for this suggestion is the reduction of health care costs in Sandusky you are mistaken. The hospitals in Sandusky unlike larger metropolitan hospitals do not have interns and residents. The salient point being that even if there were one emergency room in the Sandusky area Sandusky Memorial Hospital, out of concern for the health and well-being of its patients, would still maintain twenty-four hour physician coverage.

Kenneth B. Krakoff, D.D.S. -3-

January 13, 1975

In conclusion I would agree that this is not the time for planning by pressure groups although the HPANWO is fast taking on the appearance of one. I further agree that it is the time for statesmanship and in that light I will be happy to meet with you and other representatives of the HPANWO to discuss the future of the health care delivery system for the City of Sandusky and the surrounding communities.

Sincerely,

James K. Johnson  
Administrator

JKJ:em

cc: Casper Weinberger, Secretary, Department  
of Health, Education & Welfare  
Eugene Rubel, Director, Comprehensive Health  
Planning Service, Department of HEW  
E. Frank Ellis, M.D., Regional Director,  
Region V -- Department of HEW  
Frederick Robbins, Chairman, Ohio  
Health Planning Advisory Council  
George L. Mylander  
John Wasyluk, O.D.  
Sam Long

Casper Weinberger, Secretary  
Department of Health, Education & Welfare  
330 Independence Ave., S.W.  
Washington D. C. 20201

George L. Mylander  
155 Sunset Drive  
Sandusky, Ohio 44870

Eugene Rubel, Director  
Comprehensive Health Planning Service  
Department of HEW  
Parklawn Bldg., Room 743  
5600 Fishers Lane  
Rockville, Maryland 20852

John Wasyluk, O.D.  
540 Buchanan Street  
Sandusky, Ohio 44870

E. Frank Ellis, M.D.  
Regional Health Administrator  
Region V.  
Public Health Service  
300 South Wacker Drive  
Chicago, Illinois 60606

Sam Long  
Health Planning Association of  
Northwest Ohio  
225 Allen at W. Wayne Street  
Maumee, Ohio 43537

Frederick Robbins, Chairman  
Ohio Health Planning Advisor Council  
Dean, School of Medicine -- Case Western Reserve University  
2119 Abbingdon Road  
Cleveland, Ohio 44106

**Sandusky Memorial Hospital — Denied Approval  
By HPANWO — Granted Approval For Funding  
By Dr. John Cashman — Secretary of HEW Is Next**

The Board of Trustees of the Health Planning Association of Northwest Ohio (HPANWO), on October 21, 1974, by a 15-5 vote, recommended that the proposed project of Sandusky Memorial Hospital to add 21 medical-surgical beds, be disapproved.

Dr. Kenneth Krakoff, President of the Board of Trustees, stated that the disapproval was not intended as an attack on Sandusky Memorial Hospital or on Sandusky, Ohio. It was taken because Sandusky, Ohio is presently badly over-bedded, with a surplus of unused acute care beds existing at Providence and Good Samaritan Hospitals. No capital expenditure is required to use these facilities, just a cooperative spirit. The decision by the HPANWO's Board was to bring about further local consideration of the problem and to encourage sharing of facilities and services, as well as, promote better utilization of those already built and available services.

People who are concerned about the rising costs of health care must realize that the solution to these problems are often in our own back yards. People of Erie County do not have to look far to determine some of these factors in rising health care costs.

The HPANWO is not taking a position which is to be regarded as attacking the osteopathic medical profession or hospital. We recognize that many persons have exhibited a choice for care by osteopathic physicians, and we believe this care is of the highest quality. It is our opinion that this care, can and should, where the situation indicates, be provided in any hospital in the community, as it is in other areas of Ohio and the Nation. The HPANWO realizes that Sandusky Memorial Hospital is in need of modernization and has supported that component of the plan.

The Ohio Department of Health, itself, has said that there is a surplus of hospital beds in the County now. HPANWO's investigation has revealed that osteopathic physicians may apply for hospital privileges at Good Samaritan Hospital. A letter is on file at the HPANWO office to that effect. All general hospital facilities ought to be available to osteopathic physicians and the atmosphere ought to be one in which they feel comfortable.

The future of the matter appears to be that osteopaths and M.D.'s, and to some extent, the hospital, would rather fight than switch. The HPANWO does not feel that such an attitude is mature, reasonable, nor is the best interests of the health of the people of Erie County and the Sandusky area. In the event agreement cannot be achieved, it is the responsibility of the community to resolve this issue of what to do with the overlapping of beds.

On October 25, 1974, Dr. John Cashman received the following letter to Mr. C. L. Mylander, President of Sandusky Memorial Hospital Corporation:

November 25, 1974

Mr. George L. Mylander, President  
Sandusky Memorial Hospital Corporation  
2020 Hayes Avenue  
Sandusky, Ohio 44870

Dear Mr. Mylander:

In Re: OH11 File No.  
A4-0924-II

As Director of the Designated Planning Agency authorized by the Secretary of the United States Department of Health, Education and Welfare to carry out the provisions of Section 1122 of the Social Security Act, I wish to hereby advise you that the proposed capital expenditure referred to below has been reviewed in accordance with our procedures and found to be not in conformity with "criteria, standards and plans developed pursuant to the Public Health Service Act" (Regulations, Section 104.101(a)(2)).

In submitting this finding to the Secretary, however, I shall recommend that he not exclude reimbursement for capital expenses under Titles XVIII, XIX and XX on the grounds that Sandusky Memorial Hospital has "demonstrated proof of capability to provide comprehensive health

care services efficiently, effectively and economically, and that exclusion would discourage the operation of the facility" (Regulations, Section 100.104 (b)(2)).

Name of Facility: Sandusky Memorial Hospital  
Type of Project: Expansion and Modernization  
Estimated Cost: \$1,510,000

Although the above finding is in concert with the findings of the Board of Trustees of the Health Planning Association of Northwest Ohio, the recommendation that capital expenses be included in determining reimbursement under Federal programs is a DPA decision not reflective of the Board's intent.

The combined negative finding and positive recommendation is a result of our intention to clearly indicate the DPA's determination to support both the applicable planning documents and the planning process while at the same time recognizing the severe spatial problems at Sandusky Memorial Hospital and the fact that several unique factors are operating in the community which seem to preclude implementation of optimal planning criteria at this time.

Please observe that the DPA does not expect this decision to serve as the impetus for the continued isolated planning by area hospitals. Instead, it is hoped that the events of the past several months have vividly illustrated that community wide planning is a necessity if health care services are to be provided in an atmosphere that promotes quality yet fosters cost.

Inasmuch as Section 100.10(c) of the Regulations provides the applicant with an opportunity for a fair hearing in the case of an adverse finding or recommendation, I wish to advise you that a request for an appeal of this decision to the Public Health Council must be received by the Department within thirty (30) days of your receipt of this letter. The details of the fair hearing process can be found in the Project Sponsor Guidebook and forwarded to you earlier.

Please be advised that I have charged my staff and the Health Planning Association of Northwest Ohio to follow in the future the decree to which the joint responsibility of area-wide planning and combination of services and facilities is being achieved.

Should you have any questions, please note that the files of the DPA are now open for your inspection. If you have any questions, feel free to call or write.

Very truly yours,

John W. Cashman, M.D.  
Director of Health

cc: E. Frank Ellis, M.D.  
Regional Health Administrator  
Region V  
Public Health Service  
380 South Wacker Drive  
Chicago, Illinois 60606  
Health Planning Association of Northwest Ohio  
Mansure, Ohio 43517

In response to the letter, Dr. Kenneth Krakoff, President of the Board of Trustees of the HPANWO, wrote the following letter to Dr. John Cashman:

December 5, 1974

John Cashman, M.D., Director  
Ohio Department of Health  
P.O. Box 118  
Columbus, Ohio 43216

Dear Doctor Cashman:

I received your communication concerning the approval of Sandusky Memorial Hospital under Paragraph 1122 of P.L. 92-463 with surprise, incomprehension and considerable personal resentment.

It has been my understanding and that of the other volunteers and staff of the Health Planning Association of Northwest Ohio that there were very explicit requirements, both under this law and policies of the Department of Health, Education and Welfare, concerning comprehensive health planning, about the maintenance of high standards of health care and effective cost control measures. Consistent with this understanding, the people of this agency have undertaken several very extensive reviews and have taken and maintained some positions which were, at best, unpleasant and, in some cases, damaging to personal and business relationships. Those of us who have been involved in these endeavors, have accepted this as part of the price that must be paid in order to accomplish the planning for health to which we have all been committed.

The position which we took in this instance was arrived at after a series of very complete and difficult hearings. The denial of this application, as I hope you are aware, was based upon the conviction that if the community of Sandusky felt that Sandusky Memorial Hospital needed the additional beds it was incumbent upon that community to decide and plan for consolidation of services and/or closure of beds that are not being utilized in the other area hospitals so as to represent no net increase in bed capacity in the area. The remodeling of the hospital was not an issue; and as a matter of fact, it was suggested to the hospital that they might submit another application that encompassed the remodeling without the additional beds.

It is obvious that your position of not approving the application, but of not denying reimbursement, is de facto approval of the project. This being the case, you have not only denied approval to this agency, but have very effectively subverted the entire thrust and meaning of comprehensive health planning. Had this situation arisen in an area that had not been labeled by the Insurance Commissioner of Ohio, in agreement with our data, as the most over-bedded county in the State, there might conceivably be some justification for it. But in the present circumstance, I can conceive of no valid reason for this act other than a concession to political pressure. The merits of this particular case were very clear under the requirements of the law; Department of Health, Education and Welfare and Ohio regulations; and, indeed, common sense.

I will find it very difficult in the future to ask our committees and Board to spend the time and energy needed to complete an exhaustive review which apparently is not considered; and in the event of a negative finding, to expose themselves to the pressures and potential retaliations of disgruntled applicants.

In conclusion, I will take the opportunity to remind you that while you have had the signed contract from our agency for many weeks, we have as far not received a signed contract from your agency and will further remind you that in date we have not received funding called for under P.L. 92-603.

Our next Board of Trustees meeting is scheduled for Thursday, December 19, 1974 at 6:30 p.m. at the Stone House Holiday Inn, East 5 of the Turnpike. I will recommend to the Board at that time that we stop doing 92-603 reviews until the contract and funding are received and a firm understanding is arrived at between our Board and the OPA as to the effectiveness of our reviews.

Very truly yours,

Kenneth B. Krakoff, D.H.S.  
President, Board of Trustees

KBK:fmf

cc: Casper Weinlezer, Secretary, Department  
of Health, Education & Welfare  
Eugene Hubel, Director, Comprehensive Health  
Planning Service, Department of HEW  
F. Frank Ellis, M.D., Regional Director,  
Region V - Department of HEW  
Kenna DeShaffer, Insurance Commissioner,  
State of Ohio  
Governor John Gilligan  
Members of Board of Trustees of "B"  
Agencies in Ohio  
Frederick A. Robinson, Chairman, Ohio  
Health Planning Advisory Council

This is the story of disagreement and conflict. It is viewed by many in Northwest Ohio versus Sandusky Memorial Hospital or Toledo versus Sandusky. The facts are clear that this decision would permit Sandusky Memorial Hospital to proceed, if supported by the Secretary of HEW and by Dr. Cashman.

The HPANWO will continue to vigorously oppose this project, because it feels that the community of Sandusky, its leaders and citizens, doctors and patients, should recognize the need to work together in a cooperative spirit and for better health care and control of health care costs.

The HPANWO has never stated that we wish to prevent Sandusky Memorial Hospital from expansion, since we do recognize their need as a unique institution serving people of Northwest Ohio. We do, however, state that some use of or adapted use of existing services and facilities should be made to four additional hospital beds are constructed in the community. The HPANWO does support the need for modernization and upgrading of the Sandusky Memorial Hospital's ancillary service areas.

The HPANWO has not created the policy that we will not permit expansion of osteopathic hospital facilities, nor have we adopted a policy of forcible merger of M.D.'s and D.O.'s. We do feel that all hospitals are provided and paid for by the community and that with increasing expenses in health care, it is our responsibility to encourage a sharing consolidation to promote optimal use of these expensive facilities. Osteopathic hospitals will be approved for expansion and enlargement in the future, depending on the demonstrated need and cooperative efforts shown.

What's the next step as we see it? The HPANWO feels that the three hospitals in Sandusky, with medical staff, board and civic leadership, should begin immediate discussions on cooperative effort in several areas including emergency medical services. Our emergency room fully staffed and equipped would be superior to three. Discussions on obstetrical services and pediatric services should be taking place to determine if a plan of consolidation can be achieved.

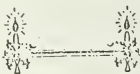
Medical staffing should be discussed and a climate of cooperation should exist between M.D.'s and D.O.'s. The HPANWO believes that the leadership exists in the Sandusky area to do just that and we pledge our assistance to that end.

The issue of what to do with remaining unused beds in Sandusky remains a serious one, which should also be cooperatively addressed. This is not the time for planning by pressure groups. It is the time for statesmanship, cooperation, and in the spirit of the season, a little real love.

NOTE: This project is one of the first in Ohio, under P.L. 92-603, which requires the HPANWO's review, the State Health Department's review and the Secretary of HEW's review, for health facility projects costing in excess of \$100,000; which changes the number of beds, or substantially changes the services in a hospital. This project was approved by the Erie County Health Planning Council and the Area-wide Facilities and Services Committee of the HPANWO. The Board of the HPANWO is the final decision-making authority in Northwest Ohio on such projects, and it recommended disapproval.

This article is presented to inform the readers of the News-letter concerning this issue. We will be glad to print reactions to this article in persons wishing to comment. All comments must be signed and we will exercise the right to choose those most representative of various points of view. The HPANWO wishes to make it clear that its policy for a bed moratorium on hospitals in Northwest Ohio is still in effect and will continue, in spite of this decision by Mr. Cashman and/or the Secretary of HEW.

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# OF GENERAL INTEREST



OCTOBER 26, 1978

DES MOINES GENERAL HOSPITAL

SPECIAL ISSUE

## CON APPROVES CV SURGERY PROGRAM

The Certificate of Need Council of the State of Iowa in a dramatic vote approved on October 26th the Des Moines General application for cardiovascular surgery. The 3-1 vote for approval came after a meeting of almost six hours of the CON Council and 1122 Review Committee. Strong opposition to approval of the project was presented by the Health Systems Agency representative and by the Chairman of the 1122 Committee. Des Moines General, however, argued that the CON law requires that providers (physicians and hospitals) and patients be given a freedom of choice between osteopathic services and allopathic services. The Hospital pointed out throughout its presentation that this is a basic right recognized and established by the Legislature and that this principle impacted on their consideration of the total project.

Mr. Kingsbury, in his comments, stated that this provision does not relieve Des Moines General from CON review nor does it mean that DMGH does not have to meet review standards. It does, however, mean that the committees must look at that issue as it relates to and perhaps modifies the other criteria for a certificate. In this particular case, for example, DMGH had established an osteopathic, unmet need that was going to be served. In addition, however, the Hospital had to demonstrate its ability to meet other CON criteria, such as financial feasibility and quality of the program.

Des Moines General also made a strong case that its program could be implemented for an extremely low dollar amount (\$80,000) and that its program would be cost-effective. The Hospital projects that it will serve 200-240 patients by three years after implementation. The Hospital also demonstrated that its program would not adversely affect the quality of care or financial feasibility of other existing programs.

### APPROVAL WAS A TEAM EFFORT

Throughout the process of planning for and seeking approval for the CV surgery program, the effort was one of a team approach. A substantial number of people from DMGH were involved in virtually all phases of the program. The "team approach" began with the Corporate Board and Board of Trustees making decisions and determining direction for the program. The Trustees also appointed a task force to look at the feasibility of developing the program, and that group met for several months early in 1978. A second administrative group was assembled in May and has worked for the past several months to work through the planning process. That group has had between 17-20 physicians and administrative people providing input and assistance.

From an administrative point of view, the team approach occurred with Mr. Kingsbury primarily handling the health planning process and presentations. Mr. Tate coordinating the preparation of the hospital for the actual operation of the program, and Mr. Lintjer providing the substantial research and written material necessary in seeking approval. In a similar manner, the legal counsel that has been involved in the CV issue has included several different people. Primary leadership in the legal area has come from Mr. George LaMarca of the Williams, Hart, Lavorato & Kirtley law firm. In addition to assistance from the attorneys and staff at Mr. LaMarca's firm, other assistance was provided by John Connolly III and Bernard Connolly, Jr. of the Connolly, O'Malley, Lillis & Hansen firm (the Hospital's general counsel). Finally, Mr. Dick Thornton from the Stewart,

In addition to the osteopathic philosophy, the Hospital pointed out that its philosophy and approach is different in that it is incorporating its program into existing services and programs of the Hospital. This philosophy is opposed to the philosophies of some CV surgery programs of creating totally separate and new facilities and services exclusively for the CV surgery effort. This approach is financially advantageous and also has the benefit of strengthening many areas of the institution.

**DRAMATIC DECISION** The decision came in a manner that could not have been more dramatic had it been directed by Hollywood! After the long and intense meeting, the discussion came to a close with an impassioned plea by an HSA Board member to deny the project. The 1122 Committee Chairman then asked for his group to make a motion regarding the application. Several minutes passed with no one making a motion or saying a word. The Chairman again asked for a motion and indicated he could wait a long time for such a motion. Again, several minutes passed with no motion and no discussion. Finally, one Board member raised several additional questions, received answers from Mr. Kingsbury and then made a motion for denial of the project. The motion was seconded and unanimously passed. That decision was and is unimportant in that it only gives approval for reimbursement for the equipment costs of the project (which are relatively minor). However, it seemed to present a bad omen for the critical decision of the CON group.

The Chairman of the CON Council, Mr. Wendell Benson, then called for his group to make a motion. Without hesitation, but in an extremely soft voice, Mrs. Frances Colston made a simple and direct motion for approval of the DMGH application for CV surgery. Although it sounds overly dramatic, the quietness of Mrs. Colston's voice and the drama of the situation had virtually everyone in the room leaning forward on the edge of their seats. The motion was immediately seconded by Mrs. Constance Cissack of Clinton and a roll call vote was demanded.

The first voter, Mrs. Colston, voted YES; the second member voted NO; the third individual, Mrs. Cissack, voted YES and the final vote was to be cast by Mr. Benson, the Chairman. The possibility of a tie vote alone was surprising, and it was then apparent that would be the worst that would occur. In a loud and certain vote Mr. Benson indicated "The Chair votes YES."!!!!

The impact of that moment cannot be described but the group as a whole literally let out a sigh of relief. The sigh was one of frustration for the few who opposed our project and one of relief and joy of the many in the room who came to support Des Moines General. Again, although it sounds dramatic, it was a moment that few of those in the audience will forget.

**POSSIBLE APPEAL** After a short recess, the Health Systems Agency representative indicated that the HSA would appeal the decision. It was unclear at that time

and unclear at the time of this writing whether the HSA Board had authorized such an appeal or whether the individual speaking has the authority to make such a decision. It is also unclear what the grounds of such an appeal will be.

In relation to appeal, Mr. Kingsbury has indicated that "The CON decision is what counts. We now have a certificate to perform cardiovascular surgery." Mr. Kingsbury went on, "I question what grounds the HSA will appeal this decision on and whether the HSA even has standing to make such an appeal. I am also encouraged by the fact that the burden of proof is now on them and, finally, I am very confident in the strength of the record we have created in gaining the CON approval." Mr. Kingsbury also indicated he anticipates DMGH will proceed with plans for implementing the surgery and will work with the State in defending any appeal that might come along.



J. LeMar, D.O., Cardiovascular Surgeon  
Team Effort continued from page 1

Heartnay, Brodsky, Thornton & Harvey firm (representing the Polk Co. Society of Osteopathic Physicians & Surgeons) provided assistance at some of the planning meetings.

As is usually the case in planning and implementing a new program, many hospital departments, department heads and employees have been involved in preparation for the program. Likewise, a team approach involving many areas and departments of the hospital will be necessary for future preparation and operation of the program.

Perhaps most impressive was the substantial number of people who were involved in the actual presentation at formal planning meetings. Mr. Kingsbury indicated that at the final CON meeting there were 19 people who provided testimony or comments in person and a substantial number of others who provided written letters of support or information. Mr. Kingsbury, Dr. Dakovich, Dr. Loerke, Dr. LeMar, Dr. K. Brown, Mr. LaMarca and Mr. Thornton all provided a part of the detailed presentation. Each covered a particular area with Mr. Kingsbury coordinating the overall presentation and providing the concluding summary.

Dr. Burt Routman made comments from the perspective of the General Practitioner who is involved in referring potential cases. He, along with Doctors LeMar and Brown and other physicians, provided the perspective of freedom of choice of physicians to select osteopathic medical care. As further physician support, Dr. David McClain (President-Elect of the Iowa Osteopathic Society) invited physicians from throughout the state to attend the meeting and represent their particular part of Iowa. Dr. Julius Abramsohn, Dr. Dan Toriello, Dr. Patrick Frankl, Dr. Roger Rademacher, Dr. Ray Avera, Dr. G. Earl Jurgensen, Dr. John Campbell and Dr. David Wilson attended the CON meeting in that capacity. Each made a short presentation in support of the project and in support of the osteopathic profession and principles being presented by Des Moines General.

A very effective letter was read from an osteopathic patient who will require cardiovascular surgery, indicating his preference for having such surgery done by an osteopathic physician. In addition, Phil Pletcher, Ph.D., made a personal presentation regarding his recently-completed open heart surgery. Dr. Pletcher also pointed out his right to choose between osteopathic and allopathic medicine and surgery.

Finally, numerous letters of support were received from physicians throughout Iowa in support of the project and the philosophy and approach being taken. Substantial use was also made of a survey of osteopathic physicians in Iowa and their feelings regarding the project. An important letter was also received from Dr. Leonard Azneer, President of COMS, in support of the program and explaining its importance to the educational goal of COMS and DMGH. Supportive letters were also provided by Mr. Dwight Reigert of Davenport Osteopathic Hospital and Mr. Darrell Vondrak of Manning General Hospital.

cost) and the need for an extensive approval process. A process that costs more to go through to gain approval than the cost of actual implementation of a project has to raise questions regarding the value and appropriateness of such a review project. Nevertheless, the health planning process is one that has been developed over many years of trial and error and consideration. It is one that is developed with the best of motives and with the community interest at heart. In the final analysis, perhaps the best summary of what occurred is that cardiovascular surgery became a symbol of what some planners saw as their obligation to restrict. The perception of some on the planning agencies was that cardiovascular surgery is extremely unique from all other kinds of surgery and is extremely expensive to implement. The planners have also struggled with a concept that says that one, consolidated unit is better than two smaller units and that competition does not work in the health care field. In the review of DMGH's cardiovascular project, planners also had concern for the "precedent" they would establish by making a positive decision. In the end, however, the CON Council looked beyond these concerns and, apparently, addressed the facts as presented, and applied the law as they understood its simple, straightforward meaning.

Whatever the causes, the process of developing the cardiovascular program and seeking its approval was perhaps the single most major project taken on by DMGH for the past twelve months.

The process began perhaps in the early 1970's when DMGH made a commitment to assist in the training of a D.O. cardiovascular surgeon. The commitment for a specific program at Des Moines General was formalized in September 1977 when the Corporate Board of DMGH resolved to do whatever necessary to initiate a cardiovascular program. Since that time presentations have been made at six different formal planning meetings to almost 100 different individuals over a span of more than two months. The formal meetings have lasted a total of almost 20 hours, and preparation for those meetings have undoubtedly been many times that amount. Numerous informal meetings were held with the staffs of the various agencies and countless individual meetings with people involved in some aspect of the project. The planning and preparation meetings within DMGH were beyond count but must have been well over 50. Mr. Kingsbury reported that the two CV groups met over 20 times and estimated that, considering the value of the participants' time, those meetings alone cost over \$20,000.

Literally hundreds of telephone calls have occurred and hundreds, if not thousands, of pages of materials prepared. Mr. Lintjer indicated that the original application was only about 40 pages long but that the file on the cardiovascular surgery planning approval now is probably about 12 inches thick.



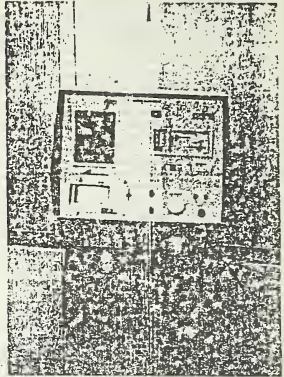
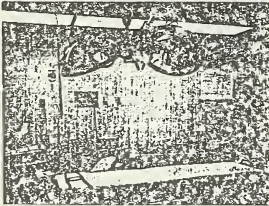
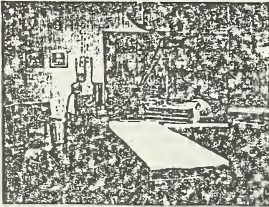
D. Kurt Brown, D.O., Cardiovascular Surgeon

## APPROVAL PROCESS: LONG AND HARD

The approval process for the cardiovascular surgery project was one that was extremely long and difficult. It perhaps is an excellent example of a need for a new perspective between the scope of a project (that is, the

## FINAL PLANS FOR IMPLEMENTATION UNDERWAY

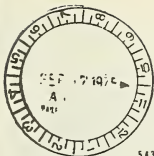
Plans were begun Friday, the day after approval was received for the implementation of the cardiovascular surgery program at DMGH. Intensive efforts for initiation of the CV surgery program were begun over six months ago and culminated in the surgery planned to occur in late June. A Board of Trustees' decision was made, however, to delay that surgery (in part at the request of the Health Systems Agency) and proceed through the planning process to seek approval. Since that decision, efforts have continued to further prepare for surgery. Mr. Tate indicated that a series of steps, meetings, and final preparations are now underway and will occur over the next several weeks. The final, necessary piece of equipment — a heart/lung machine — has now been received, and the remaining efforts are for the establishment of protocols and the coordination and final preparation of the team. Mr. Tate stated that "various 'rehearsals' and trial runs will occur with the final preparation being a detailed review of everything that will occur from the time a patient is admitted until his discharge." Plans call for the first surgery to be performed within 30 days.



## A MAJOR PRECEDENT

Over a year ago Des Moines General, along with the Polk Co. Society of Osteopathic Physicians and Surgeons, undertook efforts to have included in the Certificate of Need law a provision which protected the osteopathic profession and the freedom of providers and patients to choose between osteopathic and allopathic medicine. That effort was successful in including such a provision. The cardiovascular decision reached last Thursday was the first real application of that provision of the law. The CON Council approved the CV surgery project and thereby recognized the appropriateness of having osteopathic need as a legitimate, unmet patient need. It also recognized that the law must be applied, as it so clearly states, in such a way as to protect the freedom of choice between these two distinct medical philosophies.

Although it may be months or years before the full impact of this decision is known, it is clear that this is a decision that is of critical importance to the osteopathic profession in Iowa and perhaps the country. Other issues and decisions will come along that will more clearly and definitively define the application of the CON to the osteopathic profession, but this decision is clearly an outstanding first decision in this issue.



ART CENTRE HOSPITAL  
OSTEOPATHIC

5435 WOODWARD AVENUE • DETROIT, MICHIGAN 48202  
831-6660

M. L. PONITZ, D. O.  
MEDICAL DIRECTOR

R. S. WILDISH  
ADMINISTRATOR

September 3, 1976

Mr. Michael F. Doody, President  
American Osteopathic Hospital Association  
1211 Connecticut Avenue N.W., Suite 212  
Washington, D. C. 20036

Dear Mr. Doody:

This is in response to your Mailgram of September 1, 1976, regarding discrimination against Osteopathic Hospitals in the State Certificate of Need and planning process.

In 1974 Art Centre Hospital filed for a Certificate of Need to replace its original hospital with no increase in beds. This was denied and was appealed to the State Facilities Health Commission. Their hearing officer reversed the State Department of Health's decision and recommended approval. The State Health Facilities Commission then disapproved their own hearing officer's recommendation and Art Centre Hospital was denied. One of the reasons stated for the denial of a Certificate of Need to Art Centre Hospital was that issuance would perpetuate overbedding in an already overbedded area. At that time Art Centre Hospital was the only hospital denied and Certificates of Need had been issued to other hospitals throughout the state in similar overbedded areas.

We are currently in the process of appealing this in the Circuit Court. At that time Art Centre Hospital was the only hospital that had been denied a Certificate of Need. Since this date a Certificate of Need has been issued to a hospital in our own district for renovation. It is impossible for us to determine if Art Centre Hospital's unfortunate decision was an act of discrimination.

Should you have any questions regarding this matter, please do not hesitate to contact me.

Sincerely,

*R. S. Wildish*  
R. S. Wildish  
Administrator

RSW  
jm

ELMER J. LEE, D.O.  
PHYSICIAN & SURGEON  
MILES D. LEE, D.D.  
PHYSICIAN & SURGEON  
VIRGIL L. SHARP, D.D.  
PHYSICIAN & SURGEON  
C. JOHN NICKLE, D.D.  
PHYSICIAN & SURGEON

LEE CLINIC  
920 12TH ST.  
GREELEY, COLORADO

December 27, 1977

Mr. C. Robert Benedict  
American Osteopathic Hospital Association  
Washington Office  
603 Pennsylvania Avenue SE  
Washington, DC 20003

Dear Mr. Benedict:

Mr. Oshinsky has given me your letter of December 5, 1977.

I have taken the liberty to enclose some of the arguments we intend to present to our local HSA regarding the discriminating national health planning guidelines.

As far as personal discrimination is concerned, I was twice turned down by Weld County General Hospital. First for staff privileges and general surgical privileges and on a second application turned down for straight staff privileges. These privileges were asked for after ten years of practice in this community. This action took place about 1972.

During the process of these applications, I met with the application screening committee and Dr. Bernard Wolach, a local urologist, was so extremely rude that it was even impossible to answer the questions that were asked. His forceful accusations and interruptions made it impossible for any kind of presentation for this committee. It was recommended that I talk to the executive committee of the staff following this meeting.

In an executive committee of the staff, I was informed by Dr. Fred B. Groves, that I could never do general surgery at Weld County General Hospital unless I went to some institution and took adequate training.

The physicians that have been accepted at Weld County General Hospital have been general practitioners with one exception, an eye, ear, nose and throat man who has only had one year of speciality training and does not desire to do EENT surgery at that hospital. He has been active in assisting other eye surgeons in their surgery.

Briefly my background is as follows:

1. Born and raised in this same community.
2. In highschool, my grades were in the upper 10% of my class and I was involved in athletics where I received an award for the outstanding athlete of the highschool and during my stay was a state champion in wrestling.



Page II  
 Mr. C. Robert Benedict  
 December 27, 1977

3. I was accepted to the University of Michigan and had an athletic scholarship.
4. While attending the University of Michigan, I was number three in the national collegiate wrestling championships and received the FIELDING YOST award for combined athletic and academic achievement.
5. After three years of pre-med, I was accepted at the College of Osteopathic Physicians and Surgeons in California where I was in the upper 15% of my class and number two on the senior qualifying finals. I was president of my professional fraternity, Iota Tau Sigma.
6. I was accepted at the Los Angeles County Osteopathic Hospital for internship, a coveted internship.
7. Following my internship, I was accepted in one of two general surgical residencies available in the state of California.
8. On completion of my residency in general surgery at Long Beach Osteopathic Hospital, I returned to practice in my home-town of Greeley, Colorado.
9. During the eleven years of practice, I was accepted as a member in the American College of Osteopathic Surgeons.
10. Following acceptance in the American College of Osteopathic Surgeons, I successfully passed the boards of general surgery.
11. Following being turned down at Weld County Hospital, Dr. John Grow Sr., an eminent cardiovascular surgeon, head of the Grow Surgical Group (eight cardiovascular surgeons), allowed me to scrub in open heart surgery for one and a half years every Tuesday. He certainly accepts me and speaks well of my work. It is unlikely that a better physician exists in the allopathic profession in the state of Colorado than Dr. Grow.

In conclusion, I apologize for having to list some of the places where I have excelled over the years but it is difficult to establish any kind of discrimination unless you know something about the individual you are describing. I hope this is helpful and I would be glad to help you in any way that I can.

Sincerely yours,

*Miles D. Lee*

Miles D. Lee, D.O.

ck

Enclosure

December 28, 1977

# THE GRAND RAPIDS OSTEOPATHIC HOSPITAL

A non-profit community teaching hospital

The Honorable Frederic A. Grimm  
3278 Roosevelt Road  
Apartment T-10  
Muskegon, Michigan 49441



Dear Judge Grimm:

Recent action of the West Michigan Health Systems Agency Board with serious potential impact on Grand Rapids Osteopathic Hospital prompts this letter.

It is our understanding that a motion was defeated 14 to 13 on the question of allowing an Osteopathic Hospital obstetrical service to be exempted from the proposed Health Systems Agency goal of 1,500 minimum deliveries per year in population centers of 100,000 or more. A letter from Mr. McCarthy, our President, had drawn your attention to the fact that strict interpretation of that goal could close all but one osteopathic obstetrical service in the entire United States (actually, there are two hospital corporations which could meet this goal; however, only one is a single, unitary institution); this purely on the basis of arbitrary numbers and with no objective analysis of comparative cost or outcomes in terms of successful deliveries of healthy infants from healthy mothers. This also, despite the fact Grand Rapids Osteopathic Hospital has demonstrated mortality, morbidity and length of stay statistics equal to or better than most centers that deliver in excess of 2,000 babies a year. (See Michigan Department of Public Health "Perinatal Mortality By Hospital Birth, Michigan 1970-72" as distributed June 23, 1975.) We are hospital number 133 in this study.

The HSA Board members should be aware of the impact on services to this community should it propose to force closure of the obstetrical unit of Grand Rapids Osteopathic Hospital.

1. Closure of the postdoctoral training program for Interns. A rotating internship in an AOA approved osteopathic hospital is required for osteopathic practice licensure in Michigan. An AOA approved program requires obstetrical experience in an osteopathically oriented institution. Our Internship program currently is training 14 Interns, many of whom will become family practitioners in the West Michigan area. These Interns would be deprived of exposure to the treatment of newborn infants as well as the management of obstetrical delivery.

The only way an Intern program could be continued in the absence of obstetrical service at Grand Rapids Osteopathic Hospital would be to send osteopathic Interns to another osteopathic hospital which would meet the volume requirements of the HEW Guidelines. The one such osteopathic hospital in the country obviously cannot provide such training programs for the 1,000 D.O. graduates expected in 1978 and in future years.

1919 Boston St., S.E. / Grand Rapids, Michigan 49506 / phone (616) 452-5151



Page 2  
 Judge Grimm  
 December 28, 1977

2. Closure of the Residency training programs in Obstetrics/Gynecology  
 Our four-year residency program in this primary care specialty provides for training of three residents at a time at present. These residents are not only being trained to deliver a needed service, they participate in the teaching of undergraduate medical students, the care of patients in obstetrics and gynecologic surgery and in the operation of a clinic for the medically indigent and high risk women of the area. All obstetricians on our staff at this time are graduates of our program.
3. Closure of the OB/Gyn Clinic which would deprive high risk-mothers of pre-partum, post-partum and gynecology services, as well as a choice of physician and hospital.
4. Closure of educational classes for expectant parents which stress teaching of the physiology of pregnancy, labor and delivery as well as parenting and infant care.
5. Probable disruption of the Hospital's major affiliate status with Michigan State University College of Osteopathic Medicine. All five osteopathic hospitals with major M.S.U. affiliate status in Michigan are required to provide a teaching program for students in eight major medical disciplines including obstetrics. The HEW Guidelines, if strictly applied, would close all but one of the five major teaching hospitals affiliated with the University, creating an impossible student load for the one remaining hospital.

In addition to all of the above, closure of the obstetrics services of Grand Rapids Osteopathic Hospital would waste the many thousands of dollars recently expended to renovate our obstetrical labor, delivery and nursery areas to comply with State requirements. This renovation was done with the approval of the Michigan Department of Public Health and completed in 1976.

Therefore, we are concerned that Mr. McCarthy's letter to WMHSA pointing out one area of national concern from an osteopathic hospital standpoint was simply summarized and not mentioned at the meeting prior to Mr. Leegwater's, a vice president of our hospital, raising this issue. We had hoped our letter would make WMHSA sufficiently aware of the problem to permit opportunity for dialogue, which, unfortunately, never materialized.

We further understand that the proposed amendment ultimately considered by the HSA Board dealt with two completely separate issues, namely: the exemption of osteopathic hospitals from the 1,500 delivery rule and a proposal to permit additional CAT Scanners in the region under certain circumstances. Since these questions were not divided, it would seem difficult to assess what might have been the outcome on either had they been considered separately.

Page 3  
 Judge Grimm  
 December 28, 1977

In view of all the above considerations, we would like to ask that the matter of obstetrical delivery numerical requirements be reconsidered, at least as they apply to osteopathic teaching hospitals and in particular to Grand Rapids Osteopathic Hospital.

Given the opportunity, we would be most happy to present further testimony before the WMHSA Board regarding this vital issue.

Very truly yours,



J. Preston Miller, Chairman  
 Board of Directors  
 Grand Rapids Osteopathic Hospital

cc: Russell J. Etzel, First Vice President  
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 Honorable Stuart Hoffius  
 Frank Howell, D.D.S.  
 Paul E. Inglis  
 J. Henry Irwin  
 William Jackson

cc: Philip E. VanHoest, Executive Director  
 West Michigan Health Systems Agency

cc: Michael Dody, President  
 AOHA



## American Psychiatric Association

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March 20, 1979

The Honorable

Edward M. Kennedy

Chairman

Subcommittee on Health &

Scientific Research

Senate Labor & Human Resources

Committee

U.S. Senate

Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of the American Psychiatric Association, a medical specialty society representing over 24,000 psychiatrists nationwide, we appreciate the opportunity to set forth our views in regard to S. 544, the proposed amendments to the National Health Planning and Resource Development Act (PL 93-641). We are particularly gratified to note the inclusion in S. 544 of many of the APA-recommended changes in the planning law which will better integrate mental health planning into the process.

The enactment of the National Health Planning and Resource Development Act (PL 93-641), based in great measure upon legislation introduced by you, Mr. Chairman in the 93d Congress (S. 2994), clearly marked the start of a new era for the nation's health care through integrated planning, development and coordination of services and resources. Since enactment of the law in 1975, the American Psychiatric Association has carefully monitored and evaluated the planning law's implementation both through the Administration regulatory process and at State and local levels of activity. We have served as an advocate for active participation on behalf of the health needs of the mentally ill throughout the process of implementation.

However, as noted in our testimony last year -- and reflected in your Senate-passed bill -- our efforts to ensure credible mental health representation, staffing and linkages between the systems for the development of physical and mental health services have been continually frustrated, to the detriment of the nation's mentally ill and indeed the health of all Americans. As you recall, it has long been our view that mental health and meeting the treatment needs of the mentally ill should not be regarded, for the purposes of planning legislation, as a special interest.

Rather, such should be a clear and integrated component both of Federal, state and local health planning and service delivery and thus an essential part of the development of health systems agencies and other organizational elements established under the legislation. PL 93-641 left such integration implicit in law, which has led to the frustration of our efforts to assure a mental health component to the health planning process and structure.

Last year, we recommended numerous changes in the planning legislation to rectify these deficiencies by making explicit the critical role of the mental health care and planning systems in the health planning law. Specifically, we recommended that the Subcommittee include provisions in the bill to address:

- the lack of recognition given to the role of mental health care in the planning system;
- the inadequacy of mental health representation and staffing at each organizational level established by the legislation, e.g., Health Systems Agencies, State Health Planning and Development Agencies, the National Council on Health Planning and Development, and other advisory boards established pursuant to the Act; and
- the uncoordinated and fragmented development of physical and mental health planning functions at the Health Systems Agency and State Agency levels.

We greatly appreciate that your bill, S. 544, cosponsored by Senators Schweiker, Williams, Randolph, Pell, Cranston, Riegle and Javits, has incorporated our recommendations once again in the extension of health planning legislation. We believe these amendments represent important steps toward the realization of the objectives of the planning act.

The APA supports those provisions of S. 544 intended to further the integration of mental health planning with the health planning programs established under PL 93-641.

We hope you will make this communication part of the hearing record.

Respectfully,

*Jules H. Masserman, M.D.*  
 Jules H. Masserman, M.D.  
 President

JHM:JBC/TF



# association of american medical colleges

JOHN A. O. COOPER, M.D., PH.D.  
PRESIDENT

202: 466-5175

March 27, 1979

Honorable Edward M. Kennedy  
Chairman, Subcommittee on Health  
and Scientific Research  
Committee on Human Research  
United States Senate  
Washington, D.C. 20510

Dear Mr. Chairman:

The Association of American Medical Colleges (AAMC) is aware that the Subcommittee on Health and Scientific Research has held hearings on a number of pieces of legislation during the past week, including S.544--"Health Planning Amendments of 1979"--sponsored by yourself and other colleagues on the Subcommittee. The Association respects the importance of this bill to the future of the nation's health planning program and commends your efforts to advance it through the legislative process.

The membership of the AAMC has direct involvement in both health resources development and health services delivery throughout the nation and is therefore vitally concerned about any revision of the National Health Planning and Resources Development Act. On their behalf, the Association wishes to submit, for the record, the enclosed statement.

Thank you for this opportunity. I and members of the AAMC staff stand ready to discuss this testimony with you further.

Sincerely,

  
John A.D. Cooper, M.D.

Enclosure

**association of american  
medical colleges**

TESTIMONY SUBMITTED ON  
HEALTH PLANNING LEGISLATION  
BY THE  
ASSOCIATION OF AMERICAN MEDICAL COLLEGES  
TO THE  
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
COMMITTEE ON HUMAN RESOURCES  
U.S. SENATE

March 1979

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to testify on the renewal and revision of the National Health Planning and Resources Development Act of 1974. In addition to representing all of the nation's operating medical schools and sixty-seven academic societies, the Association's Council of Teaching Hospitals includes over 400 of the nation's major teaching hospitals. These Association members: educate the vast majority of American-trained physicians at both the undergraduate medical and graduate medical levels; conduct a substantial proportion of the nation's biomedical research; account for over sixteen percent of the admissions and approximately twenty percent of the ambulatory care services provided by non-Federal short-term hospitals; and provide a comprehensive range of patient services, including the most complex tertiary services. Because of this joint involvement in health resources development and health services delivery, the revision of the National Health Planning and Resources Development Act is of direct interest and a vital concern to the Association's members.

For ease and clarity of presentation, this testimony is organized in three major sections. The first section reviews the AAMC's historical and

continuing support for organized and integrated health planning. Section two reviews several health planning and resources development concerns of the Association and its members and suggests recommendations for clarifying and strengthening the planning program. The final section requests that this Subcommittee and its staff begin developing evaluation criteria for the performance of the health planning agencies so that future extensions or revisions of the planning act can be based on the documented successes and failures of the program.

#### General AAMC Positions

As a result of member experiences with health planning under regional medical programs, comprehensive health planning, and Hill-Burton legislation, the Association of American Medical Colleges, in 1974, determined that it was essential to have an effective and unified system of health planning on a national scale. In addition to drafting a legislative proposal which combined the planning and development aspects of RMP, CHP, and Hill-Burton, the AAMC submitted testimony to various Subcommittees endorsing major components of the bills that became P.L. 93-641.

Since passage of the health planning act, the AAMC and its members have supported implementation of the planning act by consulting with and advising HEW, state, and local agencies on its implementation; by reviewing and commenting on proposed HEW and planning agency regulations; and by participating as board and committee members on many HSAs and SHCCs. The AAMC twice supported the one-year extensions of the Act and has in the past called for its more complete implementation as a cornerstone of our nation's hospital cost containment policies.

In the past fourteen years, our nation has had four major health planning programs. Some of these have failed because they were poorly-financed, ill-staffed, or not given a chance to succeed. The Association strongly supports this Subcommittee's interest in permitting the current planning law to have an adequate opportunity to fulfill its promise by strengthening and improving existing planning mechanisms.

In reviewing the specific provisions of S.544, the Association finds several amendments which are highly desirable and supported by the AAMC: the allowance for justified inconsistencies between the Health Systems Plan and Annual Implementation Plan and the National Guidelines for Health Planning, the establishment of a program to assist and encourage the voluntary discontinuance of unneeded hospital services, the increased authorizations for Federal funding, the emphasis on coordination of planning efforts with those for mental health care, the provision for carry over of grant funds, the requirement for expanded technical assistance to the various health planning bodies, the provision requiring HSA technical assistance to project applicants, and the recognition that individuals living and working in areas covered by different HSA's are interested in serving and supporting both agencies. Each of these amendments would strengthen the existing legislation. There are, however, some AAMC concerns which are either not addressed or are only partially addressed by the amendments of S.544. In discussing these concerns and in making specific recommendations, the AAMC is attempting to further strengthen and refine P.L. 93-641.



SPECIFIC AAMC RECOMMENDATIONSAccess to Health Services

The National Health Planning and Resources Development Act seeks, in part, to increase patient access to health services. This is a laudable objective. It should be remembered, however, that access to health services is also important for medical education and biomedical research programs. Patient care, medical education, and biomedical research programs are mutually interdependent -- each requires and serves the other two as a resource. Because of this interdependence, the health services provided today also help develop health resources for tomorrow.

To ensure that health services continue to meet present health care needs and help develop future health resources, the AAMC recommends that this Subcommittee develop and approve an amendment to P.L. 93-641 which would explicitly recognize the importance of health services to health manpower education and biomedical research. The AAMC recommends that the Act be amended to encourage proposals for the location and sponsorship of institutional health services to include the proposal's estimated impact on clinical needs of medical education and medical research programs. Given that a health service area, region, or state needs a particular health service, health planning and resource development objectives can be most cost effectively served by encouraging a health service, when appropriate, to simultaneously serve as a medical care, medical education and medical research resource.

To help ensure that separate independent services are not sought exclusively for patient care, education, or research uses, the Association

of American Medical Colleges recommends that the amendment further provide that, if a health service area includes one or more accredited schools of medicine, applications for approval of health care services, which are not to be readily approved for all institutional providers, must include evidence that the service, if approved, will be available and accessible to faculty, students, and graduate medical trainees of the school(s) of medicine and teaching hospitals. Regionalizing health care services so that they may be provided at high quality and reasonable cost is an appropriate national goal. This goal, however, will be ineffectively served if high cost services provided to relatively small numbers of patients are developed in excess of patient requirements because some of the settings for these services do not make them available to meet medical education needs. All services need not support medical education programs, but enough services should support or provide access to medical education programs so that the educational system is not required to develop patient services primarily for physician education.

#### Developing Future Health Resources

Medical schools, medical faculties, and teaching hospitals serve today's patients as they develop the manpower and knowledge essential for tomorrow's health care system. To accomplish these dual missions, health planning decisions of today must not undermine the resources development programs of medical schools and teaching hospitals. Section 1513(e)(1)(B) of P.L. 93-641 states that "A health systems agency shall not review and approve or disapprove the proposed use within its area of Federal funds appropriated for grants or contracts under Title IV, VII, or VIII of this Act unless the grants or contracts are to be made, entered into, or used

to support the development of health resources intended for use in the health service area or the delivery of health services." Regulations implementing this portion of the law relative to training and research programs have yet to be promulgated. Thus, the AAMC is unclear of its ultimate effect. Moreover, the Association is unclear about the effect of Section 123(b) of S.544, an amendment which attempts to clarify the HSA's authority in this area.

The Health Professions Educational Assistance Act of 1976, P.L. 94-484 establishes programs and authorizes funds to encourage medical schools and teaching hospitals to expand family practice, general internal medicine, and general pediatrics training programs and to improve and develop ambulatory care services. The AAMC and its members are unclear as to whether the planning law at present, or as proposed, requires SHA's to review and approve grants sought under these incentive programs. Similarly, the AAMC is unclear as to whether this Subcommittee intends, by the proposed amendment, to require review and approval by the HSA of NIH grants for purposes such as clinical trials and diagnostic-specific research centers.

The nation's resources development and long-term health service needs will not be served best by requiring HSA's to regulate the nationwide resource development programs of Federal agencies which have little or no impact on the delivery of health services. The AAMC believes that Section 123 of S.544 earnestly attempts to address this situation by providing that grants or contracts under Title IV, VII or VIII of the Public Health Service Act should not be reviewed by the HSA's unless they are to be made, entered into, or used to support the development of health resources or the delivery of health services that would make a significant change in the

health services offered within the health service area. While the Association is supportive of this amendment, it recommends that the Committee Report include essential clarifying language on Congressional intent with regard to how "significant change in health services offered in the health service area" shall be defined and measured and which grants and contracts clearly meet the established criteria and would automatically be exempted from HSA review. Moreover, the Association urges that a listing of these exempted grants and contracts should be explicitly presented in an amendment to the Act.

Just over a year ago, the State of Massachusetts amended its certificate of need legislation to exempt from review medical education and/or research program (projects) which are financially self-supporting, do not result in an increase in patient charges, and do not increase the number of operating beds or the load of ambulatory services of an institution. The AAMC believes this is an excellent piece of legislation that clearly removes from HSA review medical education and research projects with only minor health service impacts, and the Association strongly recommends a similar amendment for the Health Planning and Resources Development Act.

It would be difficult to draft a suitable amendment for the broader range of impacts of Federal grants and contracts for medical education and research which do include substantial health service impacts. In lieu of such a difficult amendment, the AAMC recommends that the Committee Report accompanying any bill to amend the present health planning law include a clear statement of the Congressional intent in this area. If this recommendation is acceptable, the AAMC offers its fullest cooperation and assistance to Committee members and staff as they prepare such a statement.

### Introducing New Health Services

In the past few years, the CT scanner has received significant attention from health providers, planners, third party payors, and legislators. The CT scanner will not be the last new expensive technology; others will be developed. The health planning process can be used to thwart the introduction of such innovations or the process can be used to regulate their introduction.

As new technologies are created and introduced, HSA's will be confronted with certificate of need or service requests for which they have no established guidelines. A "Catch 22" situation could result if HSA's will not permit at least the limited introduction of new technologies, for unless the technologies are introduced there will be no experience on which to base planning guidelines and decisions. Innovations must be introduced, used, and evaluated to determine their usefulness, and HSA's must have sufficient latitude to permit such innovations in the absence of documented guidelines. Therefore, the AAMC recommends that health systems and state health plans be required to include provisions for the introduction of new medical devices and innovations which must be deployed in limited numbers to evaluate their clinical usefulness and cost effectiveness. Moreover, the AAMC recommends that the Secretary of HEW be required to perform or commission studies on approaches to the introduction, deployment, and cost-benefit analysis of expensive new medical technology.

### Regionalization and Tertiary Care Services

The AAMC has supported and continues to support the regionalization, or concentration, or health services which are of high cost or relatively

low demand. The Association is, therefore, concerned that S.544 has abandoned the language approved by the Senate during the last session of Congress which would have expanded certificate of need requirements to include "institutional health services" defined as "diagnostic or therapeutic equipment, acquired through purchase, rental, lease, or gift, valued at the time of acquisition in excess of \$150,000, used in the delivery of health care services by any person, institution, or other entity." The Association believes this provision has been weakened considerably in S.544 and would serve to undermine the true potential of certificate of need as a health planning tool and create unnecessary loopholes to the requirements for review coverage.

The present effectiveness of health planning agencies is severely handicapped by the exclusion of non-institutional services from the mandated certificate of need process. For example, in some areas where hospitals and health planners have worked cooperatively to rationally introduce CT scanners, the cost savings to the community have been significantly reduced or eliminated by physicians acquiring scanners in office-based settings not subject to review. S.544, by requiring certificate of need review only if the equipment purchased is to be used for hospital inpatients, serves to perpetuate the existing double standard rather than foster planning for optimal utilization of such expensive medical equipment in both in-patient and ambulatory care settings.

On the basis of these concerns, the AAMC reaffirms its support for an amendment to the planning law that would extend certificate of need review to the acquisition of all major medical equipment in excess of \$150,000, regardless of setting or ownership and encourages the Subcommittee to reconsider

the current proposal in favor of this clear and positive provision to strengthen the current health planning system's ability to contain costs and effectively prevent the proliferation of expensive, duplicative and unnecessary major medical equipment across the nation.

In addition, the AAMC has learned of instances where an HSA has established "conditions of approval" in reviewing requests for new services and equipment. That is, the hospital has been told by the HSA that the hospital request to initiate service A would only be approved if the hospital also agreed to implement service B, another service sought by the HSA. The Association views such "conditions of approval" as excessive uses of authority and urges this Subcommittee to address this issue by adopting an amendment which provides that, except in the evaluation of clinically interdependent health services (e.g., cardiac catheterization and open heart surgery), HSA's are prohibited from conditioning the approval of a certificate of need application upon the provider's agreement to develop one or more additional health services or programs.

Beyond the principle involved in eliminating "conditions of approval," there are practical considerations which support the same recommendation. Hospitals have limited amounts of long-term and working capital. The capital available may support adequately the development of service A but not services A and B. In this circumstance, and given that HSA's have little long-term capital to use in assisting the hospital, an approval that requires undertaking B to do A may mean that the hospital can do neither A nor B. This is a most undesirable outcome, and its cause should be eliminated.

Membership on Governing Boards

In a planning process requiring initiative and responsibility at local and state levels, it is important that governing boards broadly represent the community, including its health-related interests. Representation is especially important for medical education institutions. First, as discussed in an earlier section of this testimony, medical education programs rely on and contribute to health service programs. Including a representative from a medical school would help ensure that these interdependencies were recognized and considered in planning decisions. Secondly, as evidenced by health manpower legislation, medical education is increasingly viewed as a national resource. Capitation payments, capitation requirements, and Federal grant incentive programs all demonstrate the national character of medical education. Given the "bottom up" character of health planning and the increasingly "top down" character of medical manpower development, it is important that planning agencies include on their governing boards individuals who can bring to the board's attention national initiatives requiring local consideration. Thirdly, the medical school is in a unique position to represent health manpower education generally, for it is the medical school faculty that admits the patients who are involved in the training and education of all health science students. Under the present health planning law, HSA governing bodies must include providers who represent "health professional schools." For the reasons stated above, if a health service area includes one or more accredited medical schools, the AAMC strongly recommends that the governing board and executive committee of the HSA be required to include the Dean of at least one medical school as a voting member. Similarly at the state level, in states with one or



more accredited medical schools, the AAMC recommends that the SHCC be required to include the Dean of at least one medical school as a voting member.

Present requirements for the composition of HSA governing boards also mandate membership for providers who represent health care institutions; however, these governing boards do not have to include direct representatives from hospitals. This is a serious omission. The Health Planning and Resources Development Act relies heavily upon hospitals to achieve its goals. Hospitals are major sources of ambulatory care, emergency services, and definitive inpatient care. Tertiary care/teaching hospitals, moreover, are different from the nation's other hospitals because they also provide: regionalized, tertiary care services to significant numbers of referred patients; medical education programs from undergraduate clinical clerkships to post-graduate fellowships; and the environment for developing and evaluating new medical treatments and techniques. Because of the organizational complexity of the multi-product tertiary care/teaching hospital, it is crucial that the internal dynamics and external interrelationship of these hospitals be specifically included in HSA deliberations and planning. Therefore, the AAMC recommends that HSA governing board and SHCC requirements be changed to require that at least one member of each body be the chief executive officer of a short-term, general, tertiary care/referral hospital.

#### A CONCLUDING CONCERN

In the five years since the National Health Planning and Resources Development Act was enacted, many of the organizations required by the Act have been developed and become operational. The structure is in place. If that structure is to be retained, strengthened, and increasingly supported

with adequate funding and technical assistance, the next few years should see the planning of planning replaced by health planning itself. At its next renewal, the health planning program should be evaluated on its performance as well as its promise. For such a performance review to be objective and meaningful, criteria for assessing the program's accomplishments and shortcomings need to be established now. Otherwise, the same anecdotes and statistics may be used by program proponents and opponents as justification for terminating or continuing the program.

The Association of American Medical Colleges recommends that any legislation extending or revising health planning be accompanied by a Committee Report detailing criteria which will be used to evaluate the program for its continuation. The AAMC would be pleased to work with members of this Subcommittee and its staff to develop and evaluate such criteria for program performance.



ASSOCIATION OF REHABILITATION FACILITIES

March 14, 1979

Senator Edward M. Kennedy  
Chairman  
Subcommittee on Health &  
Scientific Research  
Committee on Human Resources  
United States Senate  
Washington, D. C. 20510

Dear Senator Kennedy:

On March 5 you and several co-sponsors introduced S.544, the Health Planning Amendments of 1979. The Association of Rehabilitation Facilities supports this bill and its recognition of the role and function of medical rehabilitation in the health care system.

The Association of Rehabilitation Facilities (ARF) is the principal association of rehabilitation facilities in the United States. Our member facilities include comprehensive rehabilitation hospitals, rehabilitation units of acute care hospitals, outpatient rehabilitation centers and treat victims of stroke, crippling disease, spinal cord injury, accidents and severe mental and emotional illnesses. Rehabilitation facilities provide a vast range of services including physical therapy, pulmonary therapy, social adjustment, vocational assessment, training and adjustment, personal care skills, and social readjustment.

Our primary concern with health planning and resources development is that it has not dealt adequately with the role and function of rehabilitation facilities in the provision of health care. Lack of direction to facilities by the states as to the development of such facilities, and lack of information in the states as to the services provided by existing facilities leaves open the potential for duplication of services and increased cost. Moreover, it fails to rec-

ognize that rehabilitation is a distinct, special form of care. The Health Planning and Resources Development Act of 1974, P.L. 93-641, was enacted to try to introduce a degree of rationality and cost effectiveness into the health care system. As the system which it authorizes evolves it should be comprehensive and cognizant of all elements of the health care system.

We are concerned that failure to recognize rehabilitation facilities in the health planning process could lead to proliferation of services, higher costs and less effective services. Final regulations to implement Title XV of 93-641 with respect to health planning were published on January 21, 1977. These do not recognize ambulatory care facilities including outpatient rehabilitation facilities as subject to the health planning process. The Department of Health, Education & Welfare cited "definitional difficulties" as justification for excluding such facilities. We believe there are well established definitions available as reflected in your bill in Section 153. All of the arguments which support the health planning program authorized by 93-641 apply to medical rehabilitation. We are also concerned about the exclusion of home health agencies. A few of our members operate home care programs and are certified as home health agencies. However, our concern stems from the need to integrate home care services into a continuum of care particularly for people with long term handicapping conditions.

S.544 recognizes these concerns in proposing the following amendments to P.L. 93-641 which ARF completely supports:

1. Section 111(c), page 10, Line 4, amending Section 1512(b)(3)(C)(ii)(II) to include rehabilitation facilities on HSA boards as provider representatives.
2. Section 118(a), page 13, line 1, amending Section 1513(b)(2) to add to the content of the health system plan (HSP), a description of all inpatient and outpatient facilities, types of care and types of services, including rehabilitation facilities and services.
3. Section 118(d), page 14, line 14, amending Section 1524(c)(2) to add to the content of the state health plan a description of all inpatient and outpatient facilities, types of care and types of services, including rehabilitation facilities and services.

4. Section 142, page 36, line 12, amending Section 1531(5) definition of "institutional health services" and including rehabilitation facilities in the definition as a type of health care facility. While it would appear that rehabilitation facilities would automatically be covered within the existing definition, the regulations under P.L. 93-641 do not include these types of facilities within this definition for purposes of the certificate of need program under Section 1523 (a)(4)(B). The amendment proposed by Section 142 would remedy the problem.
5. Section 153, page 45, line 10, amending Section 1531 to include a definition of "rehabilitation facility".

#### Discontinuance and Conversion of Hospital Services.

Section 206 of S.554 establishes a new program to encourage limiting the development of acute care hospitals and encourages the development of alternative health care facilities and services. This program would allow existing hospitals to convert part of their facility or all of their facility to another form of health care service, including ambulatory care, home health care, long-term care or other services as designated by the Secretary. Prior to any such conversion the state agency, (SHPDA), which would otherwise have jurisdiction over the service, and taking into consideration the HSA's recommendation, must make a determination that the new service is needed.

We applaud the requirement of S.554 that any conversion receive a determination of need prior to its occurrence. This determination will help assure that new services are developed only in needed sectors of the health care delivery system. Hopefully, this will prevent an over-proliferation in any one area. However, we do recommend that Section 1642(a)(1)(C), and (2)(A), be amended to include rehabilitation services as eligible services for conversion and incentive payments. As a corollary, it is important that existing rehabilitation services and facilities be recognized and assessed to determine total public need.

We would appreciate your attention to this matter and will be pleased to provide any further information.

Sincerely yours,

A handwritten signature in cursive script that reads "J. Allen Cox, Jr.".

James Allen Cox, Jr.,  
Director

JAC:lrc

**Blue Cross**  
Association

**Blue Shield**  
Association

Walter J. McNerney  
President



840 North Lake Shore Drive  
Chicago, Illinois 60611  
312/440-6010

April 4, 1979

Honorable Edward M. Kennedy  
Labor and Human Resources Committee  
United States Senate  
Washington, D. C. 20510

Dear Senator Kennedy:

This letter is being written in support of Senate Bill 544. It has become increasingly clear that the health planning process is an important element in fostering positive change in our health care system. In our opinion, provisions in S.544 improve many of the shortcomings which experience with the health planning program has revealed.

While the bill strengthens the current law, we feel that the following provisions are particularly worthy of comment:

- o With respect to the national guidelines, Sec. 119(d) of S.544 appropriately places the responsibility for implementation at the state and local levels with federal guidance.
- o Sec. 142, which expands the Certificate of Need program to include inpatient related capital acquisitions regardless of location or ownership, is a reasonable compromise to a very difficult policy question.
- o Sec. 143, which requires HSAs to consider similar projects simultaneously, should assure the selection of the best candidate to serve an identified need, and not merely the first one with an application.
- o Sec. 206, which amends Title VI of the Act by allowing for grants to support voluntary closures, conversions, and mergers of unneeded services and facilities, will help to expand and enhance the small but growing body of experience in evaluating effective ways to address these issues. Several Blue Cross Plans have been active in this area and have achieved positive results.



Commemorating fifty years  
Working for a healthier America

Senator Edward M. Kennedy

April 4, 1979

- o Sec. 118(b), which would require Certificate of Need decisions to be consistent with the State Health Plan, will provide the basis of continuity between agency decisions and long range planning.
- o Sec. 136(a), which allows for the withdrawal of a Certificate of Need if progress is not made within 24 months, will assure that needed services are developed in a timely manner.

In addition to the provisions noted above, there are other aspects of S.544 which we support. However, we have concerns which we should like to express. It is our hope that these can be addressed adequately during mark-up sessions in the Full Committee.

At present, there is a lack of clarity regarding who can be an "adversely affected" party in requests for appeals or judicial review of CON decisions and appropriateness reviews. The interpretation of who can be or is "adversely affected" is now left to state discretion, causing inconsistent policies from state to state. For example, Blue Cross and Blue Shield Plans representing their subscribers could be an adversely affected party, but in many states cannot be an appellant. We believe the interpretation of this clause should be nationally consistent and liberal in the types of organizations or bodies to which it should apply. Clearly, the general public's interests are best protected by such a policy.

Another concern we have is in regard to the bill's references on the conduct of financial analyses and studies by HSAs. A distinction must be made between what is desirable and what is practical, given the resources and time constraints of HSAs. It is not clear that an HSA can generate viable studies which show the impact of project costs and charges on the community and other providers and conduct financial viability and cost effectiveness studies under appropriateness review within which they must operate. A less specific mandate allowing each HSA to build on its strengths over time rather than be inundated with more tasks than it can be successful at would seem warranted.

With regard to HMOs, we recognize the dilemma between the desire to promote and protect HMOs on the one hand while on the other allowing the HSA an appropriate role in dealing with the diversity of providers our system of delivery acknowledges. As a matter of principle, we support HMOs and believe they should be given a fair opportunity to succeed; but we also support the role of the planning process in evaluating all proposals that, without preferential consideration, would be subject to review. If, however, preferential consideration is to be given HMOs, then HMOs should be subject to no more, and



Senator Edward M. Kennedy

April 4, 1979

no fewer, CON controls than are imposed on capital expenditures sponsored by providers in the traditional health delivery system.

The Blue Cross and Blue Shield Associations feel that consideration of the concerns expressed above will make an already desirable bill that much stronger.

Sincerely yours,



Walter J. McNerney

P.S. I am enclosing, for your information, a copy of our testimony on H. R. 3041, the counterpart bill under consideration in the House of Representatives.

WJM/jp

Enclosure

Statement of

THE BLUE CROSS AND BLUE SHIELD  
ASSOCIATIONS

on the

HEALTH PLANNING AND RESOURCES DEVELOPMENT AMENDMENTS OF 1979  
H.R. 3041

Presented to

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE  
United States House of Representatives

by

Neil Hollander, Vice President  
Blue Cross and Blue Shield Associations

March 29, 1979

Mr. Chairman and members of the committee,

I am Neil Hollander, vice president of the Blue Cross and Blue Shield Associations. We appreciate the opportunity to share with you our thoughts on renewal of the Health Planning and Resources Development Act, and amendments to strengthen its purposes.

The Blue Cross and Blue Shield Associations, which operate under a single chief executive and staff, are the national coordinating agencies for the 69 Blue Cross and 70 Blue Shield Plans in this country. The Plans provide privately underwritten coverage to about 85 million Americans, and serve almost another 20 million as fiscal agents or intermediaries for the Medicare, Medicaid and CHAMPUS programs. Thus, the Plans serve about half of the U. S. population.

The views I am about to present reflect the knowledge and experience gained by the Blue Cross and Blue Shield organizations through the administration of both government and privately underwritten health care financing programs, and through direct and indirect involvement in health planning at local, state and national levels.

#### OVERVIEW

I would first like to stress our support for the over-all health planning movement and structure created by P.L. 93-641, and to highlight those areas of most concern to us. The health planning effort to date has been devoted to development activities and the process

of gaining wide acceptance and recognition. We believe that substantial progress has been made and that the planning process has begun to demonstrate effectiveness in two key areas: cost containment and community decision-making. With regard to cost containment, the American Health Planning Association recently released a study which begins to define the savings resulting, directly or indirectly, from health planning agency activity. In many areas of the country, we are also witnessing a reduction in patient days per 1000 population along with the reduction in proposed capital investment. We believe health planning has had some effect on achieving those results, as have the activities of Blue Cross and Blue Shield Plans.

We see the process of planning as a viable means for community decision-making. In fact, the Blue Cross organization was involved in community health planning efforts as early as the 1930s, well before the establishment of formal national programs. Plans supported the process created under P.L. 89-749, are now actively engaged in the existing program and in many cases provide data and technical assistance to planning agencies. In addition, Plans encourage their staffs and board members to serve on HSA boards and committees and SHCCS. Our experiences at the local, state and national levels have convinced us that health planning can work and is increasingly accepted by consumers and providers alike. In addition, we believe that the Voluntary Effort (VE), a coalition of providers, insurers, business, labor, health care suppliers and consumers, represents a substantial commitment to health

planning. It is entirely consistent with the concepts of cooperative, local planning contained in P.L. 93-641 and the amendments of 1979. The Blue Cross and Blue Shield organizations are active participants in VE and we have been encouraged by its initial success. VE includes goals related to stabilization of the supply of hospital beds and reduction in the rate of capital investment. Moreover, hospitals have been encouraged to work closely with state and local planning agencies as they work to achieve those goals. In our opinion, VE strengthens the local and state planning processes as conducted through the structure created in P.L. 93-641 and the proposed amendments which are the subject of discussion today.

#### AREAS OF MAJOR CONCERN

Our experience with, and observations of, the health planning process have suggested that there are some critical areas worthy of concern. First is the need for a renewed emphasis on the concept of bottom-up planning. The dynamic process which this engenders in bringing about positive community planning as opposed to governmental regulatory dictum is critical to the continued success of the act. As we shall note, this concept is best addressed in terms of the use of national guidelines relative to the planning and review functions of local and state planning agencies.

The second concern is a lack of clarity regarding who can be an "adversely affected" party in requests for appeals or judicial review of certificate

of need decisions and appropriateness reviews. The interpretation of who can be or is "adversely affected" is now left to state discretion, causing inconsistent policies from state to state. For example, the Blue Cross and Blue Shield Plans representing their subscribers could be an adversely affected party, but in many states cannot be an appellant. We believe the interpretation of this clause should be nationally consistent and liberal in the types of organizations or bodies to which it should apply. Clearly the general public's interests are best protected by such a policy.

The final area of concern involves the issue of equity in the certificate of need program. With regard to HMOs, there is a dilemma between the desire to give preferential consideration to HMOs and the appropriate role of the HSA in dealing with the diversity of providers our system of delivery acknowledges. As a matter of principle, we believe HMOs should be given a fair opportunity to succeed, but we support the planning process' role in evaluating all proposals, that without preferential consideration, would be subject to review. Our position is to support modification of existing provisions of P.L. 93-641 to strengthen the effectiveness of health planning at all levels, while assuring the principle of equity in CON and other review processes.

I would like to further comment on aspects of the existing health planning law which, we feel, most need modification and to relate them to the proposed legislation now before you. Mr. Chairman, your Bill (H.R. 3041) incorporates most of the changes we will advocate in our comments.

REVISION AND REPORTING ON NATIONAL GUIDELINES

The development of national guidelines, that is, national health planning goals and standards for the supply, distribution and organization of health resources, are key components of the national health planning structure. A critical problem is the use of such guidelines in the planning and review functions of local and state level planning bodies.

The purpose of the Planning Act is to stimulate local health planning and decision-making. The federal effort should be to give health planning agencies initial advice to consider in relation to their unique local environments. Emphasis should continue to be placed on assuring a bottom-up development of health plans which reflect, to the extent feasible, the priority needs at the local level. Plans should contain local and state level health status goals, and specific supply and use requirements to attain the goals.

A major objective of the Planning Act should be to encourage providers, localities and states to plan, not simply to react. It is no secret that budgeting and planning in many health care institutions can be dramatically improved. Our efforts should focus on the local level, to make those processes effective and locally responsive so that the need to appeal to state level is the exception rather than the rule.

To insure that planning agencies are allowed to assess local needs without mandatory federal guidelines, P.L. 93-641 should be amended to delete the requirement that the Health Systems Plans (HSP) developed by Health Systems Agencies be consistent with National Guidelines. We also recommend, however, that health systems agencies provide written justification when their health systems plans are not consistent with the national guidelines.

An additional problem concerns the need for a national health policy which should, to a substantial degree, be based on consideration of the national guidelines. First, if a substantial number of health planning goals are set forth, it is important that HEW provide guidance to other federal agencies, state and local health planning agencies, etc., to insure that, where appropriate, the major goals are implemented. In this vein, Congress may wish to consider authorizing the Secretary to rank critical goals so that attention is directed toward examining the multiplicity of federal and non-federal programs that can be expected to affect them. In this way, the nation can focus on the attainment of a few important goals rather than dissipating its efforts on many goals.

Second, it is important that goals be promulgated before the standards that affect their achievement. Most recently the opposite approach was taken, creating the potential problem of lack of consistency between goals and standards. For example, pursuit of the "reduction



in infant mortality" goal might, in some locations, conflict with the standards respecting regionalization of nec-natal intensive care units.

We believe that the amendments in H.R. 3041 appropriately address the concerns we have expressed regarding national guidelines.

#### HEALTH SYSTEMS AGENCY FUNDING

Generally, current HSA funding levels appear adequate to accomplish the functions now required of them. We understand, however, that problems are being encountered by small agencies funded at the minimum level of \$175,000. Congress should assure that the minimum grant level is adequate to cover the fixed costs of smaller HSAs. DHEW should not allocate federal funds to HSAs solely on the basis of populations. It is possible, for example, that geographical factors and economies of scale achieved in larger agencies may need to be considered in determining appropriate funding levels.

Accordingly, we support the proposed amendments in H.R. 3041 pertaining to increased minimum funding levels; variable per capita funding levels as the population served by the HSAs changes; and increased aggregate funding to recognize inflation. The above comments notwithstanding, it is conceivable that HSAs may be given additional responsibilities or unforeseen extensions of current responsibilities. When that happens, additional funding should be available to assist the HSA in carrying out the identified functions.

The general adequacy of federal funding levels suggests that private provider contributions, including insurer contributions, are unnecessary to assure fiscal stability of the agencies. However, we recommend that the Act clearly specify that HSAs are allowed to provide services at cost to local persons and entities on a contract basis, with the stipulation that they not be allowed to enter into such contracts with direct providers of care. Such contract allowances have the primary benefit of enabling the HSA to respond to local health planning issues on a timely basis even when exploration of such issues cannot be accommodated within the limits of the agency's federal funding.

#### MEMBERSHIP REQUIREMENTS OF HSA GOVERNING BODIES

We believe that membership requirements for HSA governing bodies should include appropriate representation from third party payers. They represent large numbers of consumers and offer unique and necessary expertise and perspectives concerning the interrelationships of the health financing and delivery systems. In fact, in many areas, Blue Cross and Blue Shield Plans are the major purchasers of care. (Nearly half of all the privately underwritten health insurance is attributable to Blue Cross and Blue Shield Plans.) H.R. 3041 recognizes that important membership category on HSA boards, and we strongly support the language in the bill.

HEALTH PLAN REQUIREMENTS

P.L. 93-641 requires the development of Health Systems Plans (HSP) and Annual Implementation Plans (AIP) at the local level and State Health Plans (SHP) at the state level. In order to be eligible for federal grants, loans and loan guarantees under Title XVI of the Act, each state must also adopt a State Medical Facilities Plans (SMFP). Further, the Act requires that the AIP establish objectives to achieve the goals set forth in the HSP and establish priorities among the objectives. The Act also requires that the SMFP establish priorities among the projects in a state eligible for Title XVI funding.

We believe that the SMFP is essentially a duplicative effort, absorbs valuable staff resources, and its purpose can be incorporated in the State Health Plan, thus avoiding the confusion of two official state level health planning documents.

We endorse those aspects of H.R. 3041 (Section 202) which simplify the plan development process by eliminating the State Medical Facilities Plan. However, in doing so, we recommend that the State Health Plan be required to meet the SMFP requirements to inventory and rank needed services. Thus, the results of the planning process would be expressed through two key plans, the HSP and SHP, each of which would rank goals and objectives. Further, we believe that HSPs and SHPs should have uniform formats between agencies and Plans. This requirement would significantly ease the administrative process of coordination and assure comparability with respect to local and state health planning priorities.

TECHNICAL ASSISTANCE

We believe there is a need for technical assistance in the health planning system. The Blue Cross and Blue Shield Associations, and their member Plans, have been providing assistance to HSAs and their forerunners under P.L. 89-749 in the areas of data acquisition and interpretation, financial analysis and analytic concepts for health planning. We have published or sponsored a number of widely distributed documents. One contains analytic techniques used by health planning bodies in the plan development and review functions. Two others concern consumer understanding of the health planning law and participation in the health planning process. Another, prepared by the Institute of Medicine and funded by the Blue Cross Association, examined issues related to the supply and utilization of CT Scanners. There is, however, a need for a limited number of technical centers to provide health planners with a resource for development of necessary programs which might otherwise be established duplicatively by each HSA. The centers could address such issues as the development of

- (1.) consumer education programs;
- (2.) Models for inter-agency coordination (e.g. as between health planning and rate review bodies);
- (3.) analysis, interpretation and mechanisms for conducting such functions as appropriateness review; and
- (4.) exploration of the concerns surrounding new issues such as hospice services.

There are no provisions in H.R. 3041 for such centers and therefore, we support the language contained in Senate Bill 544 which retains the concept of "centers."

ISSUES CONCERNING THE CERTIFICATE OF NEED PROGRAM

One of the most critical, and controversial, aspects of P.L. 93-641 has been the provisions relating to certificate of need. We believe that a certificate of need program is necessary but that it should reflect a sense of equity among providers. Moreover, the results of this program should be held publically accountable. To these ends, we offer the following comments:

First, we feel that the Act should be amended to insure that more entities and persons are eligible to appeal state CON decisions. Specifically, we urge that appeal rights be explicitly made available to third party insurers and other relevant organizations. For example, the rate of capital investment directly affects the level and amount of payments we must make for our subscribers. In this way, an additional "check and balance" is introduced in the review and approval process, especially in cases where it is possible that an HSA and state agency have approved a project which is questionable in terms of need or affordability, or where the positions of the two agencies conflict.

Second, both the Blue Cross and Blue Shield Associations are deeply concerned with the problem of artificial shifts in the location or ownership of services between hospitals and other providers in order to circumvent regulatory controls. Specifically, the present national experience with the introduction of major medical equipment, for example the CT Scanner, suggests that a way must be found to prevent abuse of the health planning process.

We believe that the provisions in H.R. 3041 represent a viable alternative to the extension of CON to all capital expenditures regardless of location on the one hand, and the circumvention of CON and the purposes of health planning on the other. The compromise is reasonable and it should be supported by reimbursement mechanisms which provide incentives or sanctions that prevent the proliferation and unwarranted utilization of equipment and services.

Third, it is important that certificate of need controls be applied to the provision of health services in federal hospitals since they clearly affect the health resource supply and distribution requirements of non-federal facilities and services.

Fourth, the Planning Act should provide that alternative delivery systems, such as HMOs, are subject to no more, and no fewer, CON controls than are imposed on capital expenditures sponsored by providers in the traditional health delivery system. In the future there may be many other integrated health systems which will require planning review. It is our position that choices regarding method of delivery and selection of alternatives with regard to health care organizations should be locally determined on their own merits. This position gives rise to the dilemma between a desire on the part of the federal government to give preferential consideration to HMOs, and the role of the HSA in addressing community needs and alternatives to meet those needs. As a matter of principle, we strongly support HMOs, and they should be

given a fair opportunity to succeed; but we also support the role of the planning process in evaluating all proposals that, without preferential consideration, would be subject to review. HMOs already receive specific consideration in Section 1532 of P.L. 93-641 and P.L. 93-222 (The HMO Act). We strongly recommend that HMOs, or any provider, be specifically subject to any review and reporting requirement regarding capital expenditures for both inpatient and ambulatory services with which other providers must comply under Section 117 of H.R. 3041. Thus, any provider acquiring a piece of major medical equipment costing over \$150,000, but to be used in an outpatient setting, should be subject to the reporting requirements of Section 117. We believe that none of the bills now before you addresses this potential loophole adequately and we will be happy to work with Committee staff on specific language development. Such language will assure public accountability of acquisitions for outpatient settings, and promote the role of the planning function.

Fifth, we support a provision which would allow similar projects to be batched for review to assure that the best candidate to serve an identified need is selected, and not merely the first one with an application. H.R. 3041 appropriately addresses this issue.

Sixth, we support the provision in H.R. 3041 which addresses the issue of SHPDA inaction. Disapproval of an application for a CON based on inaction creates a "pocket veto" without holding the SHPDA accountable by having to specify reasons for a turndown. Therefore, we endorse

the provision which requires an automatic approval for a CON in cases where the SHPDA does not develop a formal finding.

#### APPROPRIATENESS REVIEW OF INSTITUTIONAL HEALTH SERVICE

The identification of excess capacity through HSA and state agency appropriateness review raises a set of problems that should be addressed by Congress. The Act now specifies that all institutional health services must be reviewed periodically to determine their appropriateness. It is not clear that health planning agencies, in the foreseeable future, will have the necessary resources, the technical competence or the real need to review all institutional health services simultaneously or over a short period. Accordingly, we support the proposed amendment which grants the Secretary the authority to identify specific institutional health services subject to appropriateness review. We recommend, however, that high priority be given to the institutional health services which bear the potential for significant and costly duplication, or have the potential for adversely affecting the national guidelines.

A useful role for the guidelines would be as a screen or measurement which the Secretary could apply to determine which health services should be addressed on a service, as opposed to institution, basis. Thus the mandate for conducting service reviews would be based on the national experience, but the results of the reviews would be locally determined, and necessary action taken in the context of local circumstances.



REDUCTION OF EXCESS CAPACITY

While estimates of the precise number of beds vary, there is general agreement that many areas in the nation have excess inpatient capacity. A major obstacle to eliminating excess capacity relates to the financial consequences for the provider and the fiduciary responsibilities of hospital trustees. A federal grant program for the purpose of assisting hospitals to defray certain costs associated with the closure or conversion of unneeded services might stimulate voluntary provider initiatives. The underlying assumption for this type of program is that eliminating unneeded beds or services will lead to greater cost-effectiveness in the health care delivery system and an appropriate redistribution of available capital. Since a grant program of this nature is new, it should be accompanied by a strong evaluation component to measure whether the goal of cost-effectiveness is being achieved. In this regard, it is particularly important to evaluate the cost-effectiveness of the various options of total closure, partial closure, merger and conversion.

That evaluation is a complex process and is highly dependent upon a number of variables, many of which are difficult to measure. For example, changes in hospital admission rates, mix of services utilized (inpatient vs. outpatient), costs to remaining institutions, need for alternative capital investment, etc., are among some of the important factors which must be considered. Evaluation of the cost-effectiveness of the grant program will require time. However, it is a critical element in making policy decisions regarding the long-term success of this program.

A federal grant program should provide funds for debt retirement, personnel related costs (including job retraining and re-employment assistance), facilities modification and other appropriate expenses based on the needs of each institution applying for such grants. It is likely that other organizations, such as Blue Cross Plans, will also participate in the financing of closure and conversion projects, depending on individual needs and the availability of resources. In the case of partial closures, all third-party payers should assume their share of the fixed costs through the regular reimbursement mechanism. This will require modification of Titles XVIII and XIX (Medicare and Medicaid).

Recent experience within the Blue Cross organization offers encouragement that financial incentives can be instrumental in reducing excess capacity. For example, Blue Cross of Massachusetts and Blue Cross of Northeast Ohio participated in the closure of hospitals in Boston and Cleveland, respectively. The circumstances of each case were somewhat different but the common elements were that the Plans actively encouraged capacity reduction where it was indicated and provided funds that were used in the closure process. As noted, demonstration of cost-effectiveness is difficult and the Plans along with others are currently in the process of evaluating the results.

It is our belief that Title III of H.R. 3041 provides the appropriate mechanism to encourage voluntary closure and conversion and to test the long-term impact of reduction in excess capacity.

VOLUNTARY HEALTH PLANNING

Congressional intent with respect to voluntary and cooperative health planning at the local level, as expressed in the adoption of P.L. 93-641, appears clear. HSAs, working with community resources, have a primary responsibility to develop long-range planning as expressed in the Health Systems Plans. Moreover, HSAs must prepare Annual Implementation Plans which specify how the goals described in the HSAs are to be achieved. Cooperative arrangements among providers, HSAs, third-party payers and others within the community are a necessary element in achieving stated goals. Such arrangements are particularly pertinent with respect to the development of new services and the elimination of excess capacity. The Blue Cross and Blue Shield organizations will continue to engage in these activities and will encourage others to do so as well.

Mr. Chairman, we appreciate the opportunity to appear before you to present our views. We will be pleased to answer any questions or provide whatever assistance the Committee may require in its deliberations on this important legislation.



DELTA-HILLS HEALTH SYSTEMS AGENCY, Inc. ■ P.O. BOX 701 ■ NEWPORT, ARK. 72112 ■ (501) 523-8973

JOHN E. MILLER, PRESIDENT

JOHN T. ROREX, EXECUTIVE DIRECTOR

March 21, 1979

The Honorable David Pryor  
United States Senate  
4400 Russell Building  
Washington, D.C. 20510

Dear David:

I urge you to support Senate Bill 544, the Health Planning Amendments of 1979, that was introduced on March 5, 1979. This bill will extend P.L. 93-641, The National Health Planning and Resource Development Act of 1974, under which the four Arkansas Health Systems Agencies and the Arkansas State Health Planning and Development Agency are operating.

We feel that we are performing valuable services to the citizens of our state through facilitating the development of needed health and health related programs, by containing rising health care costs through the vigorous implementation of Certificate of Need and Use of Federal Funds Review systems, and by planning for the health needs of our constituency in a comprehensive manner which is consistent with the prudent investment of tax base monies.

Last fall our Board recognized your fine leadership in Arkansas in the implementation of P.L. 93-641 and Arkansas Act 558. We hope that you will be as vigorous in your support of health planning at the national level.

If you have questions concerning this matter, please contact me.

Cordially yours,

John T. Rorex  
Executive Director

JTR/ss

CC: John E. Miller, President

Statement of the Health Insurance Association of America on  
S. 544, the "Health Planning Amendments of 1979"

This statement is on behalf of the Health Insurance Association of America which has over 300 member companies who write in excess of 80 percent of all health insurance underwritten by insurance companies in the United States.

We and our member companies have actively participated in the community health planning effort for more than twelve years. Our involvement actually began before the passage of P.L. 89-749.

As soon as the Comprehensive Health Planning Act of 1966 became law, the Health Insurance Association moved aggressively to put into action our commitment to consumer and community participation in health planning. Top executives of our companies went to several State Governors to express this commitment, and offer our help in initiating the planning effort.

In the beginning we provided seed money which helped local agencies organize and qualify for federal funding. Subsequently, we provided back-up for local planning agencies with personnel and money, which from 1973 to 1975, amounted to approximately 1.5 million dollars. Today, there are more than 250 representatives of our member companies serving on SHCCs, HSA boards, committees and subarea councils, and our Association has a central staff for technical assistance.

Insurance companies take health planning seriously. We

are committed to citizen participation in the development of effective and accountable health care delivery systems for everyone. However, we are not satisfied that the concept of community health planning has reached its potential.

Health planning has suffered growing pains, however, it is beginning to grow despite ambiguous goals and objectives, confusing federal guidance, and inadequate efforts to communicate with the public by DHEW.

Comprehensive health planning, at the areawide and state level, has been turned into a plodding, academic exercise. Elaborate inventories of resources are attempted, yesterday's needs are estimated and fed into computers to suggest planning sophistication which often results in diverting energies from the serious issues we face.

We would like to review those provisions of the Act we believe should be modified.

We believe the Act should be extended for three years with authorizations for adequate appropriations. There must be realistic financing for local planning agencies for the program to be successful.

The keystone to an effective and accountable health planning effort is across-the-board involvement at the community level of all interested parties. Insurance companies have consistently supported the concept of a major role by consumers in health planning at all levels. However, in many cases consumers have been intimidated by provider "experts". Consumer

participants, who have not had an adequate opportunity to prepare, feel no one listens to what they say. A result has been spotty participation by consumers; although, with adequate time, improved communication, clearer goals, and particularly a renewed spirit of partnership, consumer input can be a dynamic force. A consumer majority should be maintained. However, we believe third-party payers should be guaranteed a place on the HSA board; and, consideration should be given to adding criteria for eligibility to board membership which takes into consideration knowledge about health care, community needs, and community involvement. We also believe our expertise and experience would be a valuable asset to both the SHCC and the National Council. A guaranteed position on those bodies will insure our ability to participate.

Under current law HSAs have been assigned responsibilities that may be unreasonable in view of the current structure of the agencies and the resources available. We suggest a method be developed to phase-in the tasks and responsibilities assigned to HSAs in accordance with their ability to perform and allow SHPDAs and SHCCs to perform those tasks not delegated to an HSA.

Certificate-of-need programs have been somewhat effective in dealing with capital considerations. In many instances the presence of a certificate-of-need program has stopped some providers from submitting applications for "unneeded" capital projects and has resulted in modifications in many projects

which would not have been altered if the program was not in existence. However, there are still problems with the certificate-of-need program, the solution to which will add to its strength. For example, law have been passed in several states which, by specific intent and design, circumvent the state's certificate-of-need program. These special acts exempt named institutions from certificate-of-need allowing capital expansion after the state certifying agency has denied the application and the decision was affirmed on appeal.

A possible solution would be to establish Medicaid and Medicare reimbursement sanctions for new health care projects not found to be needed by the State Health Planning and Development Agency under a certificate-of-need program meeting the requirements of P.L. 93-641. Capital and operating costs associated with a project not found to be needed would be excluded from federal reimbursement under Medicaid and Medicare unless the Secretary, after consulting with state and local planning agencies, decided otherwise.

We believe the lack of a time constraint on the issuance of a certificate-of-need is a serious problem. A reasonable time frame should be placed on the duration of a certificate-of-need during which constructions must be begun or a valid contract signed for delivery of a major piece of equipment.

Major technology whose purchase, lease or installation requires substantial capital investment and/or a substantial increase in annual staffing and operating expenses should,



regardless of its setting, be included in the certificate-of-need process.

Other areas which we believe should be included in the federal certificate-of-need program are:

- a) modernization, which includes alteration, repair, remodeling, replacement and renovation of existing buildings including initial equipment and replacement of equipment of existing buildings;
- b) federal facilities should come under the review and comment process with state recommendations filed with Congressional appropriations committees;
- c) expansion of the definition of health care facility to include referral laboratories, diagnostic x-ray facilities, etc.;
- d) leasing or acquisition of sites; and
- e) home health care programs.

We also believe a certificate-of-need process tied to an effective prospective rate/budget review system will be the most effective means of controlling institutional health care costs, and note with enthusiasm Section 122 of the bill requires the coordination of these important activities.

Section 1526 of the Act should be amended to allow any state to establish or designate an agency for the review of budgets and related charge schedules and the approval or

disapproval of proposed gross revenues of health care institutions to qualify for grants under this section.

The state's plan should cover all third-party payers, and all payments should be in accord with the charge schedule approved for that institution.

Coordination between the HSAs and PSROs is important. Currently, that coordination is insufficient. To develop the HSP, the HSA must have a reasonable data base which it is unable to acquire without the assistance of the PSRO. However, PSROs strenuously resist a linking/sharing of data because of the fear that the privacy of individual medical records will not be preserved as these records are aggregated and released to the HSAs for planning purposes. The implementation of community health planning will continue to be weak as long as there is not adequate provision for the collection of accurate data for the HSAs and SHPDAs.

We recommend the following:

1. The federal government establish a minimum data set which would include: patient discharge and billing information, institutional financial information, health facilities and services information, demographic statistics and health status information.

2. The minimum data set should be implemented across the country with flexibility provided in the design of such systems for satisfying additional data requirements as they may be needed.

3. A federal agency should be designated to coordinate and oversee the data collection activities of the various states to assure coordination and eliminate duplication.

4. The states, working closely with the federal government, should establish guidelines for assuring that the information within the state is compatible with existing or established federal minimum data sets.

5. In accordance with P.L. 95-623, the states should designate an agency or responsible party to administer or be responsible for the administration of statistical activities within the state.

6. Interested parties (health data users and suppliers) should serve in an advisory capacity to the designated entity mentioned above. Each data user and provider organization should have one representative on this panel with each organization having one equal vote in regard to the activities and policies of the designated entity.

7. The advisory panel should work to assure the following:

- Nonconfidential health data is available to all data users and providers, with equal access to data limited only by the provision of guarantees of confidentiality or nondisclosure of identity of individual respondents or data subjects;
- Assure that state and local health data providers, suppliers, collectors, and users

are appropriately involved and informed of the decision-making process of the entity;

- Achieve an appropriate balance between legitimate access to data and protection of confidentiality and privacy; and
- Coordinate activities in the development of shared data systems for the purpose of reducing duplication of data collection and processing, minimizing respondent burden, encouraging maximum comparability of data.

The entire question of the state role in health planning requires further consideration. We lean toward a state health planning authority with which the local planning agencies can relate directly. The line of responsibility and authority should be to the state. However, except for states with fewer than 700,000 inhabitants, the state should not take over the whole planning process and, in any event, must allow for reasonable variation by local areas of both goals and methods of reaching those goals.

It has been our experience that the planning process benefits from an active and responsible advisory body. We believe, however, that present arrangements and practices need strengthening; e.g., the governing board composition we proposed for local agencies should also apply here.

The basic functions of the state agency appear to be workable. We feel it is important to insure that the state

agency properly consider the local plan in the development of the state plan. We do not think the state plan should be submitted to the Governor for prior approval, however, he should have the opportunity to review and comment on the state plan.

In our opinion, decertification authority must be given to state certificate-of-need agencies in order to have an effective health care cost control program. Currently, there is no way to eliminate unneeded and duplicative health services unless the provider does so on a voluntary basis. Legislation should be enacted to facilitate the phase-out of unneeded and inappropriate hospitals, to establish mechanisms to identify each such hospital, to assess its economic value, to declare that such a resource contravenes the public interest, to provide for such hospital to be retired, to compensate the institutions, and to compensate and relocate affected personnel.

Finally, we believe Sections 1513, 1524 and 1532 should make clear that the health planning agencies in the execution of their responsibilities concerning voluntary conversion, closure, reduction of capacity, and development of multi-institutional systems are exempt from antitrust action if those activities are carried out in compliance with the planning law.

No reasonable person could suggest that our health delivery system can effectively handle the needs of our citizens without an effective planning process. However, whether P.L. 93-641 is the best way to have effective health planning is a question that is too early to answer. The implementation

of the Act is still in the formative stage. Regulations are still being developed by DHEW and the force of the Act's regulatory scheme has not been fully felt. However, in many areas the HSAs influence is being recognized by state certificate-of-need agencies. The Act is still young and ought to be given the opportunity to succeed.

We have tried through our statement to be as candid and constructive as possible on this important issue expressing our feelings as well as ideas. We hope our comments will assist the committee in its deliberations.

SAMUEL M. LEVINE  
 COUNSELLOR AT LAW  
 3882 CARREL BOULEVARD  
 OCEANSIDE, NEW YORK 11872  
 516 - 766-6132

March 13, 1979

TO: Members of the United States Senate & House of Representatives  
 TO: President Jimmy Carter and Secretary Joseph A. Califano (HEW)

Re: HEALTH PLANNING FAILURES & PL 93-641

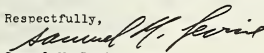
Please consider the following information and objections in developing the new amendments to the National Health Planning and Resource Development Act (PL 93-641). I request that Senator Kennedy include this letter and all of my papers previously submitted or attached, into the record of the hearing to be held in Washington on March 16, 1979. Over 100 pages of my objections, complaints, facts and information are now on file with the Senate Health Sub-committee or with the Bureau of Health Planning, Health Resources Administration, HEW. They date back to February of 1976. These same improper and illegal actions carried out by the Nassau - Suffolk Health Systems Agency and the New York State Health Planning Agencies, have been taking place in most of the other 200 regional HSA's and SHPDA's throughout the country.

I do not believe the intent of Congress to improve the health and mental health of people, to improve the health care delivery system, to contain costs and to promote equal access to quality care, has been carried out. Major surgery on the health planning system is necessary. I hope your amendments, legislative oversight action and strong administrative monitoring, corrective action and enforcement, will begin to turn things around and get better results.

There has been very little public input or support of the Health Systems Plans, Annual Implementation Plans, other Planning and Review Reports, or Grant Applications, by major organizations representing consumer interests such as the poor, the aged, the physically, mentally or developmentally disabled, labor or management.

Please advise if you desire further testimony or assistance. I would appreciate copies of any material developed on this subject, or proposed legislation or committee reports.

Respectfully,



Samuel M. Levine, JD  
 President, Health Advocates, Inc.  
 Counsel to N.Y. State Council of Organizations for the Handicapped; Federation of Parents Organizations; League of Voters for the Handicapped

SAMUEL M. LEVINE  
COUNSELLOR AT LAW  
3882 CARREL BOULEVARD  
OCEANSIDE, NEW YORK 11972  
516 - 766-6132

March 12, 1979

TO: New York State Health Dept., Att: Comm. Axelrod & Mr. Berman, OHSM  
New York State Hospital Review & Planning Council  
New York Statewide Health Coordinating Council  
New York State Health Planning Commission

TO: U.S. Dept. of Health, Education & Welfare, Health Resources  
Administration & Health Care Finance Administration

RE: HEALTH PROJECT REVIEWS BY THE NASSAU-SUFFOLK HEALTH SYSTEMS AGENCY

I urge that you disregard the decisions and recommendations of the N-S HSA (and other HSA's with similar failures, improper and illegal actions, for the following reasons:

1. GUIDELINES & REGULATIONS DISREGARDED. Poor attempt to obtain specific facts that show compliance by applicants. Many laws not enforced including the Rehabilitation Act, Sec. 502 on Architectural Barriers, Sec. 503 on Affirmative Action in Employment and Sec. 504 on Discrimination of the Disabled. They merely accept applicants self serving replies with no presentation or evaluation of facts of compliance. Protection of patients rights, quality of care and treatment, treatment plans, appropriateness, level of care, utilization review, patient abuse and mistreatment, are all subjects poorly monitored and evaluated in reviews.

2. STAFF QUALIFICATIONS, experience and job qualifications are poor. They failed to hire people with the special skills, licenses, knowledge and experience in the planning, development, operation and administration of the facilities and services under review or being planned. They are utilizing unlicensed, unqualified staff, carrying out functions required to be licensed, qualified, experienced in various disciplines, including- doctors, nurses, therapists, administrators.

3. PUBLIC PARTICIPATION. Many day meetings held, so that working consumers can not attend and participate. No home rule. No convenient, centrally located meeting places, near facilities under review or centrally located in respective counties. Poor reach out efforts. Very little public input or support for Health Systems Plans, Annual Implementation Plans, Grant Applications, Review Manual or Review Reports, by major organizations representing consumer interests, such as the poor, the aged, the disabled, labor or management.

4. COST CONTAINMENT: Very poor effort. They have approved millions of dollars of hospital expansions, increased medical-surgical beds, new, expensive equipment and support services and facilities. Please investigate all approvals in the past three years of reviews.



Re: Health Project Reviews

March 12, 1979

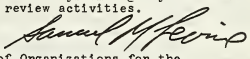
5. CONFLICTS OF INTEREST: Many providers, who are usually in the majority, are sitting on committees, councils and Governing Board as consumers. Many providers violate the conflict of interest rule when they vote on and review applications involving their professional colleagues, competitors, related staffs, and other relationships, having a financial or other interest in the outcome or results of the reviews. Providers control committee actions. Doctors and hospital administrators vote on hospital and other applications affecting colleagues and competitors in other facilities.

An unwholly alliance exists between the Nassau-Suffolk Health Systems Agency and the Nassau-Suffolk Hospital Council, since the Hospital Council's Executive Director is the former Deputy Director of the Health Systems Agency with an office across the hall in the same building.

6. OTHER REASONS: Contained in my statements attached, dated July 25, 1978 and March 16, 1978; as well as others on file with the US Dept. of Health, Education and Welfare, Health Resources Administration and Bureau of Health Planning.

Please take appropriate action to eliminate the improper and illegal actions by the Nassau-Suffolk Health Systems Agency and other HSA's with similar actions, in their review activities.

Samuel M. Levine, JD  
 President, Health Advocates  
 Counsel to N.Y. State Council of Organizations for the  
 Handicapped; Federation of Parents Organizations;  
 League of Voters for the Handicapped



CC: Senator Edward Kennedy; Senator Jacob Javits  
 State Senator Tarky Lombardi, Senator Frank Padavan,  
 Assemblywoman Elizabeth Connally, Assemblyman James Tallon  
 Nassau-Suffolk Health Systems Agency, ALPHA  
 Consumer Coalition for Health, Wash, DC.

SAMUEL M. LEVINE  
COUNSELLOR AT LAW  
3851 CARREL BOULEVARD  
OCEANSIDE, NEW YORK 11572  
816 - 756-5132

July 25, 1978

To: Hon. Joseph A. Califano, Secretary of Health, Education & Welfare  
To: Dr. Henry A. Foley, Administrator, Health Resources Administration  
Re: COMPLAINT AND CHARGES AGAINST THE NASSAU-SUFFOLK HEALTH SYSTEMS  
AGENCY

This letter is a supplement to the letter of June 9, 1978, to add to the objections, charges and complaints contained therein. for which a hearing has been requested.

1. GOVERNING BOARD: No consumer members who are welfare recipients or with poverty level incomes; no consumer members who are physically or mentally or developmentally disabled or their parents or identifiable advocates or representatives of major county or regional consumer groups for the disabled; no representatives of major county or regional senior citizen consumer groups (except on Suffolk attorney designated a County Executive appointee); no consumer representative of labor organizations. The health politicians who control the governing board and election process, saw to it that Robert Moss, representing the paraplegic veterans, was eliminated from the board, by refusing to re-nominate him for a new term, because of his advocacy on patient rights.

2. STAFF: No staff member with a high level and extent of knowledge professional qualifications, expertise and experience in the planning, development and administration of large, sophisticated facilities and service systems for acute, ambulatory, long term, environmental, rehabilitation and mental health care and treatment.

3. COST CONTAINMENT: Very poor efforts in determining ways and means of containing health care costs or in reducing the extremely high cost of health and mental health care and treatment in the region. No review of hospital costs, medical fees, administrative waste, etc.

4. FEDERAL LAWS: Very poor attempt to incorporate into plans and carry out implementation activities needed to obtain compliance by health care providers, of the many federal laws, regulations, guidelines and state plans relating to the problems and needs of the handicapped, particularly, The Developmental Disabilities Act, the Rehabilitation Act, the Education for Handicapped Children Act, and the Community Mental Health Centers Act.

5. HEALTH POLITICS AND PROVIDER CONTROL: Allowing providers to dominate and control governing board and committee meetings, plans and decisions. Allowing health politicians who traditionally controlled the health planning system in the past, to continue their undue influence and behind the scenes contacts, which lead to policy and action decisions protecting their interests (eg: Long Island Jewish - Childrens Medical Center proposal).

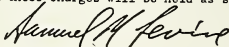
6. CRISIS ISSUES: Failing to solve the crisis issues facing the region or take effective action to arrive at solutions to the nursing home bed shortage, the dumping of patients into and out of state psychiatric institutions, the lack of comprehensive ambulatory health facilities, the lack of geriatric facilities and services, environmental emergencies, the high cost of health care; and others.

7. PUBLIC PARTICIPATION: Failing to obtain representation and participation of major consumer groups affected by applications under review or plans and action items at hearings and committee meetings. Gag rules that unfairly limit public input and participation.

8. OTHER CHARGES: Set forth in previous letters from me or Federation of Parents and other organizations relating to the operations and activities of the Nassau-Suffolk Health Systems Agency.

9. I hope the hearing on these charges will be held as soon as possible.

Respectfully,



Samuel M. Levine, JD; Counsel to Health Advocates, Federation



# Health Advocates, Inc.

2175 Wantagh Avenue

/ Wantagh, N. Y. 11793

/ (516) 781-1500

PRESS RELEASE for March 16, 1978

Re: GRANT APPLICATIONS BY HEALTH SYSTEMS AGENCIES

The Health Advocates organization, jointly with the Long Island Regional Council of the Federation of Parents Organizations for the State Mental Institutions, made up of parents and relatives of persons with handicapping conditions, has begun a campaign to challenge the permanent and full designation of the Nassau-Suffolk Health Systems Agency (HSA). The Wantagh based group today stated that they support the conclusions and objections which their counsel, Samuel M. Levine, an Oceanside attorney, presented to the HSA governing board on March 9, 1978 (see statement attached).

The following is a summary of some of the objections Levine set forth in his letter to Secretary Joseph Califano, U.S. Department of Health, Education and Welfare and Governor Hugh Carey: wasteful and extravagant expenditures (\$1.3 Million for 78-79) for salaries, supplies, rentals, travel; the lack of qualified, experienced planners; a small, unrepresentative governing board; political "matching games" in an illegal election process for board membership; poor public participation and involvement or support for its plans; thirteen years of failures by HSA and its predecessor, producing "snow storms of paper", but accomplishing little in terms of substantial and important changes and improvements in the health and mental health systems; a poor work program which does not accomplish many changes and actions, except to assess, study and review existing programs and gather more data; failure to solve the crisis issues facing the region, such as the nursing home bed shortage, the dumping of patients into and out of state psychiatric institutions; the lack of comprehensive ambulatory facilities; the lack of geriatric facilities and services; environmental emergencies; the high cost of health care; and others.

Levine stated that "the greatest reason for rejecting and disapproving the HSA grant application to be submitted to HEW, was the failure to identify and incorporate into these HSA plans, the goals, objectives and activities needed to implement federal and state laws and plans affecting the handicapped and disabled".

He stated that "consumers have a right to expect substantial improvements and changes in the health and mental health care delivery systems. We will take all possible legal, administrative and public action necessary to obtain the rights and benefits that health and mental health care providers are obligated to honor and furnish".

Agnes McClean, President, Health Advocates

Kathleen Braille, President, Long Island Regional Council,  
Federation of Parents Organizations,

SAMUEL M. LEVINE  
COUNSELLOR AT LAW  
3862 CARREL BOULEVARD  
OCEANSIDE, NEW YORK 11572  
816 - 766-6132

October 31, 1977

TO: Senator Edward Kennedy, Chairman, Senate Committee on Health

Re: HEALTH PLANNING AND THE HANDICAPPED

I am enclosing a small sample of over 100 pages of letters and statements I have submitted to Secretary Califano and Governor Carey, indicating the defects, improper actions, violations of law and mistakes I have found in the implementation of the new National Health Planning and Resource Development Act, PL 93-641. These same violations and mistakes are being made in many of the 200 regional Health Systems Agencies in the nation. I urge that you adopt amendments that will correct these problems. I also urge an investigation of my charges against the N-S HSA, particularly the discrimination of the handicapped.

Some of the changes I recommend are as follows:

1. Mandating a minimum governing board sixty seats designated for specific provider and consumer groups, including: senior citizens, disabled persons (physically, mentally & developmentally), welfare recipients, minority groups, education, labor, management, clergy, etc.

2. Mandating the inclusion in the Health Systems Plans and the Annual Implementation Plans, goals and objectives which will implement all health related federal programs and legislation, particularly the laws affecting the handicapped (Rehabilitation Act, Developmentally Disabled Act, Education for all Handicapped Children Act, Community Mental Health Centers Act).

3. Mandating consumer majority control and vote on all governing board and committee meetings and actions; and standards of public participation.

4. Mandating minimum goals for results and accomplishments, in given time frames, especially on national priorities such as community mental health systems, education for the handicapped, an end to the discrimination of the handicapped, patients rights, etc.

5. Establishing a new Accreditation and Monitoring Commission at the state and federal level to replace AMA and AHA controlled Joint Commission on Accreditation of Hospitals.

There are other recommendations that I have, which I would like to present to your committee in oral testimony personally, at a hearing or committee meeting.

I would appreciate hearing from you on these matters.

Respectfully,

  
Samuel M. Levine, Esq.

SML:L



# Health Advocates, Inc.

2175 Wantagh Avenue

/ Wantagh, N. Y. 11793

/ (516) 781-1500

PRESS RELEASE

for

March 16, 1978

Re: GRANT APPLICATIONS BY HEALTH SYST EMS AGENCIES

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Agnes McClean, President, Health Advocates

Kathleen Braille, President, Long Island Regional Council,  
Federation of Parents Organizations,

SAMUEL M. LEVINE  
 COUNSELLOR AT LAW  
 3882 CARREL BOULEVARD  
 OCEANSIDE, NEW YORK 11572  
 516 - 766-6132

November 1, 1978

Hon. Jimmy Carter  
 President of the United States  
 White House  
 Washington, DC

RE: HEALTH PLANNING IN NEW YORK STATE AND ITS HEALTH SYSTEMS  
 AGENCY REGIONS

Dear President Carter:

I hereby appeal to you on behalf of the health and mental health care consumers of New York State, to review and correct the health planning problems and mistakes that I previously brought to the attention of Secretary Joseph Califano at the Department of Health, Education and Welfare. Unfortunately there has been no response to my requests of June 9, 1978 (Health Planning in N.Y.State) or November 17, 1977 (State Health Coordinating Council) from Secretary Califano nor has any corrective action been taken. Your efforts along with Mrs. Carter's desires to improve the health and mental health care delivery system, to protect human and civil rights and contain the inflationary, unconscionable increases in health costs, are threatened and damaged by the failure to properly implement the health planning law at the state and regional levels.

Secretary Califano has taken no action to order Governor Carey to reorganize the illegally constituted State Health Coordinating Council.

New York State's health planning organization and operation is a bureaucratic nightmare. It is a four headed monster, with two bodies and sixteen arms moving around, usually in an uncoordinated manner, operating behind closed doors in an "ivory tower" known as the Rockefeller Plaza Tower Building (which is part of a two billion dollar monument to the waste of taxpayers funds). Public and consumer input and participation is very poor and un-solicited.

HEW has not taken any action against the 8 regional Health Systems Agencies in New York State, which are also violating the law and congressional purposes and intent. (See attached Health Advocates Press Release of March 16, 1978).

I am very disappointed at the failure of the State's health planning agencies and the regional HSA's to take effective and successful action in the implementation of the four major federal laws affecting the 18% of the population with a physical, mental or developmental disability, namely:

The Developmental Disabilities Act; The Education for All Handicapped Children Act, The Community Mental Health Centers Act and the Rehabilitation Act and its Section 502 on Architectural Barriers, Section 503 on Employment and Section 504 on Discrimination. The State Health Action Plan and State Health Plan outline failed to identify the implementation of these laws and programs as priority matters for state action. The record of N.Y. State in the implementation of these laws is poor indeed. I also believe that N.Y. State has failed to obtain millions of dollars of federal funds that are available under a myriad of federal laws and programs relating to the improvement of health and mental health facilities and services.

The mental health system has been deteriorating, particularly for the 40,000 in-patients in the state's mental and developmental centers. Parents and consumer groups have been forced to institute many court actions for damages or injunctive relief or protection of civil rights. These court actions are a result of wrongful deaths, poor quality of care and treatment, mistreatment and abuse of patients, shortage of staff, poor facility conditions, poor supervision, administrative deficiencies, violations of federal and professional regulations, laws and standards, refusal to discharge patients and other violations of the rights of patients. Thus the taxpayers of this state are forced to pay for a one billion dollar mental hygiene system that is wasteful of the health, welfare and in many cases, the lives of disabled people, as well as tax funds.

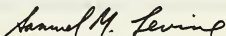
Court actions are now pending on many wrongful deaths of patients; conditions and treatment of patients at Creedmore and Hoch-N.E.Nassau Psychiatric Centers, Willowbrook and Suffolk Developmental Centers; private damage actions (eg. Bartlett v. State, a \$175,000 award); class actions for violations of civil rights (Project Release v. Prevost); and others too numerous to mention.

HEW is also engaged in a survey and investigation of these charges and complaints brought by parent groups and myself at Pilgrim, Hoch-N.E.Nassau, Creedmore, Bronx and Manhattan Psychiatric Centers.

New York State is also violating the Health Planning Law by allowing providers to dominate and control the state and regional health planning agencies and process. Few consumer representatives of the poor, the aged and the physically, mentally and developmentally disabled are involved. Rights of health care consumers, rehabilitation and acute psychiatric services, among others, are victims of the state health planners omissions.

I therefore urge that you direct the White House health staff to look into these complaints about HEW and New York State's health planning and mental health problems and mistakes. I would be pleased to meet with them personally. Please advise what action will be taken on this request.

Respectfully yours,



Samuel M. Levine, JD ; Counsel to Health Advocates; Federation of Parents; League of Voters for the Handicapped





# Health Advocates, Inc.

2175 Wantagh Avenue

/ Wantagh, N. Y. 11793

/ (516) 781-1500

PRESS RELEASE

for

March 16, 1978

Re: GRANT APPLICATIONS BY HEALTH SYST EMS AGENCIES

The Health Advocates organization, jointly with the Long Island Regional Council of the Federation of Parents Organizations for the State Mental Institutions, made up of parents and relatives of persons with handicapping conditions, has begun a campaign to challenge the permanent and full designation of the Nassau-Suffolk Health Systems Agency (HSA). The Wantagh based group today stated that they support the conclusions and objections which their counsel, Samuel M. Levine, an Oceanside attorney, presented to the HSA governing board on March 9, 1978 (see statement attached).

The following is a summary of some of the objections Levine set forth in his letter to Secretary Joseph Califano, U.S. Department of Health, Education and Welfare and Governor Hugh Carey: wasteful and extravagant expenditures (\$1.3 Million for 78-79) for salaries, supplies, rentals, travel; the lack of qualified, experienced planners; a small, unrepresentative governing board; political "matching games" in an illegal election process for board membership; poor public participation and involvement or support for its plans; thirteen years of failures by HSA and its predecessors producing "snow storms of paper", but accomplishing little in terms of substantial and important changes and improvements in the health and mental health systems; a poor work program which does not accomplish many changes and actions, except to assess, study and review existing programs and gather more data; failure to solve the crisis issues facing the region, such as the nursing home bed shortage, the dumping of patients into and out of state psychiatric institutions; the lack of comprehensive ambulatory facilities; the lack of geriatric facilities and services; environmental emergencies; the high cost of health care; and others.

Levine stated that "the greatest reason for rejecting and disapproving the HSA grant application to be submitted to HEW, was the failure to identify and incorporate into these HSA plans, the goals, objectives and activities needed to implement federal and state laws and plans affecting the handicapped and disabled".

He stated that "consumers have a right to expect substantial improvements and changes in the health and mental health care delivery systems. We will take all possible legal, administrative and public action necessary to obtain the rights and benefits that health and mental health care providers are obligated to honor and furnish".

Agnes McClean, President, Health Advocates

Kathleen Braille, President, Long Island Regional Council,  
Federation of Parents Organizations,



July 25, 1970

To: Members of Congress and State Legislatures  
 To: Hon. Joseph A. Califano, Secretary of Health,  
 To: State Health Planning & Development Agencies  
 To: Local Health Planning Agencies

SAMUEL M. LEVINE  
 COUNSELLOR AT LAW  
 3882 CARREL BOULEVARD  
 OCEANSIDE, NEW YORK 11572  
 516 - 768-6132

Re: HEALTH COST RESOLUTION # 13

I offer the following Resolution #13 for your approval and implementation by all national, state and local health, mental health regulatory, supervisory and planning agencies.

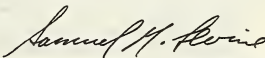
WHEREAS, the skyrocketing costs of health and mental health care, treatment and services has imposed a crushing burden and hardship on health care consumers and taxpayers; and there is a need for action to limit and reduce these costs; now therefore be it RESOLVED:

1. That the Congress, State and Local Legislatures and Chief Executives take emergency action to approve plans and laws that establish effective health cost limits on health care expenditures, fees, health insurance rates and re-imbursements;

2. That HEALTH COST REVIEW COMMITTEES be established in all health planning regions, with a majority of consumers, including the poor, the aged, the handicapped, labor and management or their representatives, to carefully and expeditiously review these health care expenditures, fees, rates and reimbursements, with a view toward limiting increases and if possible, reducing these costs, while maintaining and improving the quality of health and mental health care, treatment and services.

3. That Congress enact as soon as possible, a bill mandating a national health plan and insurance plan, which will improve the health and mental health care delivery system to the point that all Americans will be afforded high quality, cost effective, comprehensive health and mental health services and facilities regardless of their station in life or ability to pay.

Respectfully submitted,



Samuel M. Levine, JD, Counsel to N.Y. State Council of Organizations for the Handicapped, Health Advocates, Federation of Parents; Member, Health Systems Agency, Nassau County Council

SAMUEL M. LEVINE  
 COUNSELLOR AT LAW  
 3882 CARREL BOULEVARD  
 OCEANSIDE, NEW YORK 11572  
 516 - 766-6132

June 9, 1978

TO: Hon. Joseph A. Califano, Jr., Secretary, Health, Education & Welfare  
 Department, USA  
 TO: Dr. Henry A. Foley, Administrator, Health Resources Administration  
 RE: HEALTH PLANNING IN NEW YORK STATE AND THE NASSAU-SUFFOLK HSA

This is an appeal to you to correct the improper and illegal actions taken by the New York State Health Planning and Development Agency, the State Health Coordinating Council and the eight regional Health Systems Agencies in New York State, particularly the Nassau-Suffolk HSA.

I was pleased to learn that a reorganization is taking place in Washington in the Bureau of Health Planning and Resource Development. I hope that a similar reorganization of personnel and functioning, takes place in the New York region.

I request a review of over 100 pages of complaints and objections previously submitted, which were ignored or rubber stamped with approvals of plans and grants involved in these complaints. Please review, in particular, the three memos attached, dated March 9, 1978 (Grant Application), August 23, 1977 (Health Systems Plan) and November 10, 1977 (Annual Implementation Plan).

I urge that you direct Governor Carey to reorganize the State Health Coordinating Council to remedy the objections I have made in the memo of November 17, 1977 (copy attached). The SHCC is dominated and controlled by Dr. Kevin Cahill and his hand picked appointees from the medical profession, the health provider and other interests, who do not represent the broad spectrum of consumer or provider interests, particularly the poor, the aged and the physically, mentally and developmentally disabled. Their planning efforts to date are extremely poor, as is their public participation policies and actions.

I would like a hearing on my charges that the elections held by the Nassau-Suffolk HSA in 1977 and on June 8, 1978 were illegal. Also, on my charges that the poor, the aged and the disabled consumers are not properly represented on their governing board. I will prove that eight out of the sixteen so-called consumers, on the governing board, including four "consumers" elected on June 8, 1978, are actually providers. This hearing should take place in New York City or Long Island and be presided over by a high level official in the Office of the Secretary or the Health Resources Administrator. The New York regional health planning staff can not objectively or properly determine the issues raised in these memos and correspondence.

Respectfully,

*Samuel M. Levine*  
 Samuel M. Levine, JD; Counsel to Health Advocates, L.I. Regional Council, Federation of Parents; Treasurer, N.Y. State Council of Organizations for the Handicapped

SAMUEL M. LEVINE  
 COUNSELLOR AT LAW  
 3882 CARREL BOULEVARD  
 OCEANSIDE, NEW YORK 11572  
 516 - 766 6132

July 25, 1978

To: Hon. Joseph A. Califano, Secretary of Health, Education & Welfare  
 To: Dr. Henry A. Foley, Administrator, Health Resources Administration  
 Re: COMPLAINT AND CHARGES AGAINST THE NASSAU-SUFFOLK HEALTH SYSTEMS AGENCY

This letter is a supplement to the letter of June 9, 1978, to add to the objections, charges and complaints contained therein, for which a hearing has been requested.

1. GOVERNING BOARD: No consumer members who are welfare recipients or with poverty level incomes; no consumer members who are physically or mentally or developmentally disabled or their parents or identifiable advocates or representatives of major county or regional consumer groups for the disabled; no representatives of major county or regional senior citizen consumer groups (except on Suffolk attorney designated a County Executive appointee); no consumer representative of labor organizations. The health politicians who control the governing board and election process, saw to it that Robert Moss, representing the paraplegic veterans, was eliminated from the board, by refusing to re-nominate him for a new term, because of his advocacy on patient rights.
2. STAFF: No staff member with a high level and extent of knowledge, professional qualifications, expertise and experience in the planning, development and administration of large, sophisticated facilities and service systems for acute, ambulatory, long term, environmental, rehabilitation and mental health care and treatment.
3. COST CONTAINMENT: Very poor efforts in determining ways and means of containing health care costs or in reducing the extremely high cost of health and mental health care and treatment in the region. No review of hospital costs, medical fees, administrative waste, etc.
4. FEDERAL LAWS: Very poor attempt to incorporate into plans and carry out implementation activities needed to obtain compliance by health care providers, of the many federal laws, regulations, guidelines and state plans relating to the problems and needs of the handicapped, particularly, The Developmental Disabilities Act, the Rehabilitation Act, the Education for Handicapped Children Act, and the Community Mental Health Centers Act.
5. HEALTH POLITICS AND PROVIDER CONTROL: Allowing providers to dominate and control governing board and committee meetings, plans and decisions. Allowing health politicians who traditionally controlled the health planning system in the past, to continue their undue influence and behind the scenes contacts, which lead to policy and action decisions protecting their interests (eg: Long Island Jewish - Childrens Medical Center proposal).
6. CRISIS ISSUES: Failing to solve the crisis issues facing the region or take effective action to arrive at solutions to the nursing home bed shortage, the dumping of patients into and out of state psychiatric institutions, the lack of comprehensive ambulatory health facilities, the lack of geriatric facilities and services, environmental emergencies, the high cost of health care; and others.
7. PUBLIC PARTICIPATION: Failing to obtain representation and participation of major consumer groups affected by applications under review or plans and action items at hearings and committee meetings. Gag rules that unfairly limit public input and participation.
8. OTHER CHARGES: Set forth in previous letters from me or Federation of Parents and other organizations relating to the operations and activities of the Nassau-Suffolk Health Systems Agency.
9. I hope the hearing on these charges will be held as soon as possible.

Respectfully,



Samuel M. Levine, JD: Counsel to Health Agency

SAMUEL M. LEVINE  
 COUNSELLOR AT LAW  
 3882 CARREL BOULEVARD  
 OCEANSIDE, NEW YORK 11572  
 515 - 765-6132

March 9, 1978

TO: Governor Hugh Carey, State Health Planning Commission, State Health  
 and Coordinating Council  
 Hon. Joseph A. Califano, Secretary of Health, Education & Welfare

From: Samuel M. Levine, JD, Member, Board of Visitors, Pilgrim Psychiatric  
 Center; Treasurer, N.Y. State Council of Organizations for the  
 Handicapped; Counsel to League of Voters for the Handicapped,  
 Health Advocates, Federation of Parents; Member, Nassau-Suffolk  
 Health Systems Agency, Nassau County Council

RE: GRANT APPLICATIONS BY HEALTH SYSTEMS AGENCIES

It is recommended that you disapprove the grant applications for full designation of the Health Systems Agencies in N.Y. State, as well as their Health Systems Plans and Annual Implementation Plans. This conclusion is based on our close involvement in the work of the Nassau-Suffolk Health Systems Agency, a review of their HSP AND AIP AND GRANT APPLICATION, as well as a review of the SHCC staff reports of four applications approved by the SHCC on March 7, my review of the Western N.Y. HSA plans and comments from people in the state regarding the operations and work of the other HSA's. My review of the N-S HSA plans dated Aug. 23, 1977 and November 10, 1977, previously submitted to you, should be considered also. The following comments relate specifically to the Nassau-Suffolk grant application, but they are applicable to the other HSA applications.

BUDGET AND STAFF: I am shocked and dismayed at the wasteful and extravagant expenditure of taxpayers funds, set forth in their budget. The approval of these budgets might conceivably result in taxpayers actions against governing board members and bureaucrats who approve these budgets. Salaries to an executive director of \$40,000 plus 27% in fringe benefits (20% is the norm), for a total of over \$50,000 seems excessive, especially in light of the job descriptions and qualifications that may be weak and inadequate to meet the challenges of the job. An administrative monstrosity is established to expend the \$1.3 million dollars in government funds allocated. Equipment and furniture spending is uncontrolled (Eg: filing cabinets at \$470 each; 4 memory typewriters rented at \$13,000 per annum; \$25,000 for travel; \$33,000 for phones; \$55,000 for printing and copying). These sums support 26 professional staff people and 17 support or clerical workers. The staff structure is poor. It is missing qualified, experienced planning experts in ambulatory care, acute care, mental health, long term care, rehabilitation, rights of consumers & patients. No separate departments or staff divisions are established for these functional areas. Planning and review responsibilities are separated functions with different "jacks of all trades" serving as staff.

**ORGANIZATION:** No effort has been made to correct the mistakes and failures in the creation and operation of these HSA's, as outlined in the previous letters of Aug. 23 and Nov. 10 and the many other letters previously forwarded to you. Discrimination of the poor, the aged and the handicapped consumers, still exists. The 30 person governing board is very un-representative of the various provider and consumer constituencies that exist in this bi-county region of 2.7 million people. The election process is still poorly carried out. A political matching game now takes place in the nominating process. The membership committee will meet behind closed doors to decide what outside candidates will run against an incumbent board member (if he or she chooses to stay on), and will, at the same time, determine what category of interest they decide will be represented by that particular seat. The governing board by laws, cleverly and intentionally failed to designate the categories of interest for each consumer seat, so that the health politicians could play their matching game. They use a "consumer at large" designation for each seat, rather than a designated constituency such as the mentally disabled, the poor, senior citizens, etc. It is interesting to note that the "window dressing" sub area county councils have designated categories of interest for each consumer and provider seat. Thus, the poor, the aged, the physically and mentally handicapped, labor, etc., all have identifiable seats on the county council, but not on the governing board. County Council replacements must be made within the same category of interest. On the other hand, governing board members do not know what seat they hold and for what category of interest. When it suits their purpose, and in order to deprive certain candidates and interests of a seat on the board, they will fill a vacancy by announcing that the replacement was selected to give representation to a certain group of people (eg: the minorities from the east end of Suffolk) and they will reject another interest group (eg: the mentally disabled from Suffolk).

**PUBLIC PARTICIPATION:** Consumer control of the regional HSA's (including Nassau-Suffolk), is a myth and a public relations fabrication. The providers and special interest health politicians control the governing boards, committees, the activities and decisions of these health planning bodies. The N-S HSA is a prime example of this situation. A review of their attendance records and minutes will prove this point.

Federal and state bureaucrats overlook these and other violations of the law and improper practices, poor planning activities and actions. Public outreach efforts have been ineffective. The so called public hearings on the AIP and Grant Application resulted in few appearances and little public comment. Public support for the HSP, the AIP and the grant application, is very poor. No endorsements are attached or were received from local governmental bodies, consumer, civic, fraternal, religious, or professional associations. Most of them are not even aware of the existence of the HSP, THE AIP or the grant application. Many important meetings are held during the day to prevent working consumers from attending.

**PROGRESS AND WORK PROGRAM:** The aforementioned letters outline many deficiencies in the HSP, the AIP and the grant application. For 13 years, the federally funded planning bodies (Comprehensive Health Planning Councils, the Regional Medical Plans and now the Health Systems Agencies), have deliberated, spent millions of taxpayers dollars and produced snow storms of paper, but accomplished little in terms of substantial and important changes and improvements in the health and mental health care delivery system. The work programs set forth in the grant applications are designed to produce more blizzards of paper (1.3 million dollars worth in Nassau-Suffolk), but very little in specific results, changes and improvements

in the health and mental health systems. Throughout the work programs, we see the words -- "assessment", "study", "review", "data gathering", "revise plans", etc. Technical assistance is to be provided, but by whom? Staff expertise and experience in the planning and development and administration of health and mental health related facilities (including hospitals, nursing homes, clinics, etc.), is questionable.

No appropriate plans have been devised in the past two years of HSA life, to meet and resolve the crisis issues that exist in our region, including -- nursing home bed shortages; acute psychiatric bed shortage; the quality of care and treatment and the incarceration of patients in State Psychiatric and Developmental Centers; the poor system of emergency care for psychiatric patients; the dumping of patients from general hospitals to state institutions; the dumping of discharged patients into impacted communities like Long Beach and Bayshore, without proper after care facilities and services; the lack of comprehensive ambulatory care facilities; the lack of geriatric facilities and services; environmental emergencies; the high cost of health care ; and others.

Perhaps the greatest reason for rejecting and disapproving these grant applications, is the failure to identify and incorporate into these plans, the goals, objectives and activities needed to implement federal and state laws and plans affecting the handicapped or disabled. They include, the Developmental Disabilities Act, the Education for all Handicapped Children Act, the Community Mental Health Centers Act and the Rehabilitation Act, including its Section 504, which prevents the discrimination of the handicapped. The lack of recognition and protection of the rights of consumers or patients, is another fatal defect in these plans and grant applications. A very poor attempt has been made to incorporate and integrate state and local Health Department and Mental Health Department plans and responsibilities into these HSA plans.

I must inject an objection which, in the past few months has become a source of personal concern to me, my family and the family of my good friend Morton Posner. I must object to the inadequate treatment given to the problems of patients afflicted with cancer. Even the limited attempt by the Nassau-Suffolk HSP & AIP to deal with this subject, falls far short of the mark. I will shortly make some comprehensive recommendations to add to these plans, in order to deal with the cancer problems that have become a major issue throughout the country.

I am still waiting for some response and action from the SHCC and its committees regarding the previous ideas and objections previously forwarded to them. It is regrettable that they approved four HSA grant applications without questioning or challenging the deficiencies and mistakes outlined.

We consumer advocates will insist on high standards of performance and results by these HSA's , the State planning bodies, the federal, state and local agencies and private health providers. We have a right to expect substantial improvements and changes in the health and mental health care delivery system. We will take all possible legal, administrative and public action necessary to obtain the rights and benefits that health and mental health care providers are obligated to honor and furnish.

Respectfully submitted,

*Samuel M. Levine*



# Health Advocates, Inc.

2175 Wantagh Avenue

/ Wantagh, N. Y. 11793

/ (516) 781-1500

November 10, 1977

TO: Secretary Joseph Califano, U.S. Dept. of Health, Education &amp; Welfare

TB: N.Y. State Health Coordinating Council and Planning Commission

Re: MENTAL HEALTH PLANNING and the ANNUAL IMPLEMENTATION PLAN OF THE  
NASSAU SUFFOLK HEALTH SYSTEMS AGENCY

We offer the following information with regard to the mistakes and improper actions taken by this HSA in the development of its AIP. It is further evidence to deny permanent designation and reject its HSP & AIP.

1. The staff and a small provider working group (with no consumers), selected only 14 HSP objectives for the AIP, out of over 51 HSP objectives or sub-goals and 13 recommended long range actions. They included 16 short range actions under the 14 objectives. Mental Health consumers and advocates in this region, want all goals, objectives and long range actions in the HSP, considered and acted upon and not ignored. We also believe that the HSP is also deficient and omits many goals. (See my August 13, letter).

2. There are far greater crisis issues that need immediate attention, that are being ignored by the committee and the HSA. These include: Conditions at Hoch-N.E.Nassau Psychiatric Center (a state institution in Suffolk County serving Nassau County patients); the need for acute psychiatric beds in Nassau County and stopping the dumping of Nassau patients into poor state institutions in Suffolk County; the tragic consequences of unlawful and improper practices and policies in admission or in many cases, rejection of psychiatric patients in general hospitals, and their referrals to state institutions; the immediate need for treatment facilities and services in Long Beach, Bayshore and other communities impacted with the mentally disabled; the violations of patients rights in local general and state hospitals and institutions; the lack of proper care and treatment in local and state psychiatric and mental health facilities; the urgent need now for large numbers of community residential facilities and beds; and others.

3. They failed to take any action to review and integrate the 1978 Nassau and Suffolk Counties mental health plans into the AIP; or to review and integrate the regional plans of the State DMH Director (especially the Plan for Children and Adolescent Services); thus perpetuating the four planning and delivery systems that exist in this region.

4. They are continuing to ignore the need for implementing the major federal laws affecting the disabled, namely; the Developmental Disabilities Act; the Rehabilitation Act; the Education for all Handicapped Children Act; the Community Mental Health Centers Act.



5. They have not resolved the question of the HSA's role in Mental Health planning or the coordination of planning with County, State and private planners.

6. They refuse to establish planning sub-committees for each County and develop a separate AIP for each county, thus violating Home Rule principles.

7. They are utilizing staff which does not meet the need for having one exceptionally qualified, broadly experienced, top level, well paid director for mental health planning and review and development, who can provide the staff leadership in a coordinated, one system approach to mental health planning.

8. The Chairman of the Mental Health Task Force has arbitrarily and unreasonably ruled consumers out of order or curtailed their input or refused to have our concerns attended to.

9. The October 6, 1977 meeting did not have a quorum present, since only 5 members, mostly providers, were present.

10. The committee, controlled by providers, is limiting consumer input by meeting during the day so that working consumers can not attend; and merely reacting to planning papers and drafts developed by staff and a small working group or sub-committee of 4 providers and no consumers.

12. Their draft AIP and its timetable does not have the support of the parents and relatives of patients and other interested consumers, who are disappointed at the HSA actions to date.

#### Re: AMBULATORY CARE PLANNING

I am shocked and dismayed at the way the Ambulatory Care Planning Task Forces have been operating and the decisions and priorities they have agreed to, for the AIP. The Nassau and Suffolk committees are operating with a small handful of 5 members, with a provider majority. AIP decisions have been made without the input of consumer representatives of the poor, the aged or the handicapped. The Nassau meetings have been held on the North Shore, which violates the "centrally located" rule.

Their priorities fail to establish an urgency about the immediate need for developing comprehensive ambulatory care facilities and services for thousands of poor, aged and handicapped who are -right now- vegetating, regressing and dying in their homes or slum dwellings, because of the unavailability of accessible, quality care and treatment.

They rejected my attempts to establish immediate planning action, in the form of a local planning council in one target area (Long Beach), as a first step in serving these unfortunate consumers.

They established a priority of gathering more data and statistics, despite the fact that millions of dollars of consumer-taxpayer money was spent in previous years gathering such data and statistics.



I object to the fact that staff is deciding the priorities, which are being reacted to and rubber stamped by a handful of providers who control these committees, thus controlling the health planning mechanism for 2.6 million people.

These committees should be required to make on site visits and hold meetings at the facilities for which they are developing plans; that every effort be made to obtain representation and input from consumers representing all special constituencies; that meetings be held in the evening at centrally located places; and priority attention be given to crisis issues that exist.

RE: LONG TERM CARE

The Long Term Care Committee efforts to establish their AIP, also gives me cause for concern. At their meeting on October 18, 1977, I detected no sense of urgency or planning effort about the emergencies and crisis issues that we face in our nursing homes; the terrible conditions in our Psychiatric Centers; the failure to provide decent residential and health facilities for our elderly in target areas such as Bayshore and Long Beach; the elderly patients languishing in hospitals instead of nursing homes or other alternative placements; or the protection of the rights of consumers.

RE: HEALTH SYSTEMS PLAN

I am sadly disappointed at the fact that the U.S. Dept. of Health, Education and Welfare and the State Health Planning Commission have already approved the Health Systems Plan for Western New York and will undoubtedly be "rubber stamping" their approval of the HSP for Nassau, Suffolk. Both of these HSP's are totally incomplete and unacceptable so far as the needs and problems of the physically, mentally and developmentally disabled are concerned. Both plans fail to give proper recognition or establish goals to implement the monumental new federal and state laws, regulations and plans affecting the disabled and handicapped, including: Education for all Handicapped Children, PL94-124; the State Plan and the State Education Law, Article 89; The Rehabilitation Act of 1973, PL93-112; The Developmental Disabilities Act of 1975, PL94-103; The Community Mental Health Centers Act, PL94-63; The Governor's Annual Health Messages for '75 '76, & '77. The plans do not have special chapters or sections on the specific and special needs and problems of the disabled, as well as the poor and the aged.

There is no indication that local legislative and executive branches of government have held hearings, provided input or approved or support the plans. Likewise, there is no indication that State regional directors and offices and County Departments of Health and Mental Health and their advisory boards, have been involved in, helped develop and approve these HSP'S. On the contrary, the Long Island Regional Director of the Dept. of Mental Hygiene of the State, informs me that he has no intention of preparing a review, a critique or approval of the plan. Is it possible that these HSP's are to be ignored and without legal standing so far as the mental health care system and County and State governments are concerned? Are they to be omitted from the County and State mental health plans now mandated by new State legislation?

Both plans fail to present proper goals and objectives that would enable local HSA's to make any kind of contribution to controlling costs and improving the quality of care and treatment in the health and mental health fields. Your efforts to control costs and improve the quality of care are doomed unless you force these HSA's to do their job in these two areas. Their predecessors, the Comprehensive Health Planning Councils, the Regional Medical Programs and the Health and Hospital Planning Councils likewise failed in the past ten years in cost and quality control and system planning in general.

Both plans are very weak in dealing with the following subject areas: rehabilitation; education; housing; environment; transportation; manpower needs;

The Nassau-Suffolk plan gives priority treatment to only four problems: infant death, motor vehicle accidents, cancer and heart problems; but not to mental health, developmental disabilities, the physically disabled or the poor or the aged. We will not approve such a limited set of priorities, which ignore our crisis problems, especially the mentally disabled and elderly people who have created special problems in communities like Long Beach and Bayshore.

Both plans are extremely weak in failing to present a full and comprehensive set of goals and objectives in the areas of human rights and patients rights. The first draft of the Nassau-Suffolk plan did not set forth any goals and objectives, but merely included a short, totally inadequate paragraph about "common concerns" in the "linkages" section. Thus it appears that the recognition, implementation and enforcement of patients rights and human rights in hospitals, nursing homes, mental institutions, schools and other health related facilities, will not be properly handled or planned for by these HSA's. Brief mention of the need for "advocacy mechanisms" by 1982, does not satisfy our need for advocacy services and protection to all types of consumer groups now, not five years from now. They have failed to recognize the need for new accreditation and monitoring mechanisms to prevent fraud, waste of taxpayers money or to expose bad conditions in health facilities and the poor quality and level of care and treatment. A replacement must be found for the ineffective, Joint Commission on Accreditation of Hospitals, now controlled by the American Medical Association and the American Hospital Association.

They failed to recognize the critical professional and clinical manpower needs that exist, especially in mental hospitals and ambulatory care facilities.

In Acute Care, the Nassau-Suffolk plan calls for 643 new medical-surgical beds (now designated "pipeline" beds), despite the fact that there may be an over abundance of these beds now and certainly in the future when new ambulatory care and group health facilities are established. We seem to still be following the needs and dictates of hospital boards and staffs, rather than honestly establishing the changes needed in this area and recognizing the realities of existing need, high cost and wasteful practices. Both plans ignore the President's and the Governor's leadership and policies in trying to reduce the cost of acute and ambulatory medical and health care. There is very limited and inadequate treatment of the health insurance field and the problems that exist in the third party payment practices and failures. They have failed to establish a goal and policy whereby governing boards of hospitals and health related facilities and agencies would be mandated to include identifiable consumer advocates and representatives of the poor (including racial and ethnic minorities), the aged and the physically, mentally and developmentally disabled.

The Ambulatory Care plans do not present solutions to the substantial and critical needs that exist today, among the general population and the exceptional consumers of health care (the poor, the aged, and disabled). They have not mandated or planned for more and better ambulatory clinics and facilities by existing hospitals and health facilities. Emergency room ambulatory care will still be a way of life. They made a poor attempt to recognize and plan to meet the problems and needs of communities impacted with large numbers of medically indigent consumers.

They failed to establish proper goals to involve the schools or industrial or occupational health care systems in the overall health systems plan.

In Long Term Care, they failed to recognize and plan to solve the crisis that exists in the shortage of skilled nursing and health related facility beds; or the scandals involving their ownership and operation; or the waste of taxpayers funds; or the poor level and quality of care. They failed to include a goal calling for more non profit organizations such as churches, labor unions, civic, veteran and service organizations to operate and control such facilities, instead of the profiteers and speculators now in the business.

They failed to include a goal to establish several comprehensive, geriatric day care programs in various parts of the region, where needed, now. The Nassau-Suffolk plan merely calls for one day care geriatric program by 1982.

In Mental Health they failed to include proper goals that will solve the critical problems that exist, as previously set forth hereinabove. These include : an improved community service system; protection of patients rights; improvements in the level and quality of care, especially institutional care; residential facilities and programs; rehabilitation and employment; education; advocacy; accreditation and monitoring. It is still not clear whether we will have three separate mental health systems (state, county and private) or one, as contemplated by new legislation. The HSP's certainly do not make any contribution to resolving that conflict. No solutions are offered to the problems of financing the mental health system and relieving local governments of the cost of transferring the institutional system to a community service system. They have not mandated this transition, but merely made it conditional on certain prerequisites. They have failed to develop a plan which would result in providing acute and long term psychiatric care for Nassau County patients in hospitals and facilities located in Nassau County. Now they are sent from 20 to 40 miles away to State institutions in Suffolk County. There is poor recognition and planning for the role played by the private mental health care providers in the overall mental health system of care. They failed to consider a goal of having community hospitals provide the necessary psychiatric beds to replace state institutional beds.

Their public participation goals and policies are weak. They failed to consider the idea of creating a Health Cost Review Board to assist in the cost control objectives; or to create a Health Care Quality Review Board to assist in improving the level and quality of care in all health and mental health facilities and agencies .(Consumer majorities on both).

The Health Systems Plan in Nassau-Suffolk was developed under structural and organizational defects and improper actions which have been spelled out in previous correspondence. An appeal to the Secretary of HEW is now pending on these matters. A cloud exists over the entire HSP, which will be approved and implemented by a small, elite, powerful group of 30 people who do not represent the various constituencies and interest groups in two counties with populations of 1.4 million (Nassau) and 1.3 million (Suffolk).

*K. Braille, President Agnes McLean, President*



## MINNESOTA HEALTH SYSTEMS AGENCY SIX

208 East Third — P.O. Box 156 — Redwood Falls, Minnesota 56283 — Phone: 507-637-3575

March 27, 1979

The Honorable Edward M. Kennedy  
Senate Office Building  
Washington, D.C. 20510

Dear Senator Kennedy:

As the National Health Planning and Resources Development Act (P.L. 93-641) is being considered for revision and extension during this session of Congress, we would like to ask for your support of this important legislation.

As pointed out by the Comptroller General's Report to Congress on the Status of the Implementation of the Health Planning Act, "it is too early to determine the effect of planning agencies in achieving the objectives of the Act. Such an analysis cannot be done for several more years." Nevertheless, even at this early stage of the health planning program, significant achievements have been accomplished.

For example, in the area of cost containment, according to a survey conducted by the American Health Planning Association in the fall of 1978, the local Health Systems Agencies (HSAs) have already prevented unnecessary capital expenditures of \$3.4 billion in the period from August, 1976, to August, 1978. It should be noted that this survey included only 81% of the country's HSAs. Furthermore, the survey did not provide estimates of savings in future operating costs. Such savings would typically be many times the value of the capital investment itself.

Of a per capita basis, the planning agencies prevented \$26.45 in unnecessary capital investments, as compared to the total per capita investment in health planning of only \$1.16, a savings of over \$15 for each dollar spent.

Our Agency has prevented unnecessary capital expenditures in our health service area of almost \$18 million, or a savings of over \$37 for each dollar spent on this Agency.

It should also be noted that these achievements represent merely the tip of the iceberg, reflecting only a small (but easily measurable) segment of the overall activities of the health planning agencies.

Unfortunately, the efforts of many HSAs have been seriously hampered, and further significant progress prevented, by inadequate and inequitable funding levels. It is our best estimate that a minimum basic capitation support level of 70-75 cents will be required to enable our Agency to effectively assume all

The Honorable Edward M. Kennedy  
 March 27, 1979  
 Page Two

of its responsibilities, to be sufficiently flexible to serve the different needs of each community, to perform essential public relations and education activities, and to be professionally competent and knowledgeable in legal as well as technical matters.

If Congress wishes to continue the health planning agencies as "an experiment," then the agencies cannot assume the role they should and must to be effective. Adequate funding of such agencies will promote full function for the life of the proposed renewal legislation, and permit adequate budgetary controls based on sound business principles and directed toward long range outcomes. In order to enable the HSAs to perform the functions required in the Health Planning Act, adequate and equitable funding levels are absolutely essential.

The 1980 Health Budget rationale states that "the most critical cost containment aspect of the health planning process is the capacity of health planning agencies to understand local conditions and to devise appropriate strategic responses. There is a great need to strengthen this capacity at the State and local level." Yet, the budgetary commitment toward meeting this great need is a token 1.3% increase over the 1979 budget, which actually represents a substantial decrease from an already totally inadequate funding level.

The funding problems have been particularly serious for rural HSAs. In fact, for some agencies, the situation is rapidly approaching a critical level. The funding formula for HSAs prescribed by P.L. 93-641 is based on population. As a result, the amounts received by HSAs range from a couple of hundred thousand to several million dollars. Yet, all are expected to perform essentially the same tasks of planning, review, resources development, data collection and analysis, and public involvement and education.

A formula based on population size alone may make some sense when we are talking about the direct provision of health care services. But the HSAs do not provide direct health care services. They plan, review, educate, and act as catalysts to get others to carry out the plans, once their planning process has ascertained the needs, goals, and objectives of the people they serve. The cost of providing such services are not strictly proportional to the size of the population of the planning area being served. Generally, it will take nearly as much time, data, and staff expertise to plan for 500,000 people as it does for 1 million people.

This problem is frequently aggravated by the size of the geographic area served by many of the rural HSAs. It is usually more difficult to obtain data in such areas, technical and human resources are frequently not easily available or accessible, means of communication are often inadequate, and effective coordination more difficult to achieve because of the scattered population structure and the large number of units of local government. Travel expenses for staff, Governing Body, and committees will be substantial. Personnel costs will often be higher due to difficulties in attracting and retaining qualified personnel. In short, cost of operations will often be relatively larger in rural areas, with fewer resources available.

The Honorable Edward M. Kennedy  
 March 27, 1979  
 Page Three

Although project reviews may generally occur more frequently in metropolitan areas, the difference in the number of proposals will not be proportional to the difference in population size. The cost of the projects to be reviewed may also be larger in metropolitan areas. However, it will usually require as much time, data, and expertise to review a 30 bed modernization project as a 100 bed proposal. In fact, it may be easier to carry out the review function in a metropolitan setting than in a highly rural area, because of difficulties in data gathering and analysis, the impact of the decision on the community in question, and the problem of reconciling the jurisdictional, economic, social, and political interests affected by the decision.

These factors clearly suggest the need for a modification of the funding allocation formula for HSAs. It is, of course, very difficult to devise a formula which adequately reflects all of these factors, and, at the same time, is simple enough to be practical. However, significant improvements could be achieved by using a formula where the funds would be distributed based on a sliding scale per capita rate, supplemented by an additional amount related to the size of the geographic area being served.

For example, the formula might read:

70¢ per capita - first million population,  
 50¢ per capita - second million population,  
 30% per capita - over 2 million population,

plus an additional

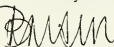
5¢ per capita - land area 10,000-20,000 square miles,  
 10¢ per capita - land area over 20,000 square miles,

It may never be possible to overcome all funding allocation problems, but it should be possible to improve the present funding formula so that it will not unduly handicap HSAs which cover large land areas and/or scattered populations, in their efforts to successfully carry out the intent of the Health Planning Act.

We would hope that the health planning legislation will receive the attention and support it deserves during the present session of Congress. A strong and adequately funded health planning program would provide this Nation with perhaps the most effective, appropriate, and acceptable means available for improving our health care system and for containing the cost of providing health care services.

We would strongly encourage you to support the renewal of the Health Planning Act. In particular, we would like to ask for your support of adequate and equitable fundings levels for HSAs.

Yours very truly,



Bjorn Larsen  
 Executive Director

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# National Association of Counties

Offices • 1735 New York Avenue N.W., Washington, D.C. 20006 • Telephone 202/785-9577

March 21, 1979

The Honorable Edward Kennedy  
United States Senate  
432 Russell Senate Office Building  
Washington, D.C. 20510

Dear Senator Kennedy:

Attached to this letter is a copy of our proposed amendments to the National Health Planning and Resources Development Act of 1974. These amendments were approved by our Health and Education Steering Committee on March 11, 1979. The proposed amendments closely follow the bills passed last year by the Senate and the House Interstate and Foreign Commerce Committee. We believe that our proposed changes improve the present law. Since they have been considered and, in most cases, accepted by either the House Interstate and Foreign Commerce Committee or the Senate Human Resources Committee, they should permit the rapid passage of this important piece of health legislation.

The National Association of Counties is strongly in support of a truly local health planning system. These agencies, we believe, should play a key role in the containment of costs and the implementation of a national health financing system. Under the Hospital Cost Containment Act of 1979, which we support, we are also concerned that these agencies have the capability and mission of monitoring the "dumping" of high cost patients on public hospitals. They must also provide the stimulus for providing services in underserved areas and encourage the kind of public health and prevention activities which offer the greatest potential for long term improvement in health status.

However, planning in general and health planning in particular are intensely political activities. It is the process by which scarce resources are allocated -- the classic definition of politics. As such, the process of planning is far more than the mere development of technically competent plans, reports and analyses. Of at least equal importance is the development of a broad based community support for the planning process and for the specific policies which are embodied in the health systems plan and annual implementation plan. Without broad public support, HSAs cannot withstand the political pressure which inevitably will result from policies aimed at making the health care system more efficient and effective.

There is clearly no large constituency now in existence for restricting the health care system. If this constituency is to evolve, it must be developed at the local level -- and the HSAs are critically important participants. These



The Honorable Edward Kennedy  
 March 21, 1979  
 Page 2

local agencies must be credible and have the understanding and, hopefully, the support of all segments of the community which have an interest in improving the efficiency and effectiveness of the health care system.

Our concern is that elected officials and other major groups are alienated from the health planning process. Their alienation is caused by the structure and processes of many HSAs which are established to avoid the significant and meaningful involvement of the local officials and other major consumer and provider groups. Yet, their involvement and political support are critical for the successful implementation of the plans and policies of the HSA.

First, we believe that the public regional planning body, joint powers agency or unit of local government should have the authority to approve the major policy documents of the agency, as well as the budget. It should also have the authority to set the rules and regulations of the agency and appoint the governing body for health planning. Presently, after the governing body is appointed, the HSA has nothing to do -- yet, it is responsible for the policies which are inherent in the HSP and AIP.

S. 544 gives the governing board of the HSA the power to appoint the governing body for health planning and approve the agency's budget. Budget control, we think, is critical, and we fully support the inclusion of this provision. In addition, we support the formalization of the board's authority to establish the agency's rules and regulations. However, if the governing board is to be truly accountable and if the public agency is to play a truly meaningful role, then it must have the power to approve the HSP and AIP and the criteria for project, institutional and appropriateness review. The language we propose allows for careful consideration of the views and concerns of the volunteer governing body for health planning while still placing ultimate authority in the sponsoring city, county, or region for final approval.

A second major concern relates to the closed, often self-perpetuating nature of many HSAs. The present law allows a subcommittee of the existing governing body to choose new members of the body. In addition, it allows virtually any member of a group to represent that group. Therefore, any minority member can be deemed to represent minorities, any elderly person can represent the elderly, and so on. The problem of elected officials is particularly difficult. A public health nurse, a faculty member from a public community college in health sciences, or even the coroner can be considered a public official representing the county. A study of the first 136 HSAs showed that only nine per cent were local elected officials. (No subsequent data is available.)

As a consequence of these problems, we feel that local governments should be represented by individuals who they choose and not those who are screened and appointed by the governing body, often without the knowledge or consent of local government. We have not proposed any specific quota of "public official" representation. Rather, we suggest that the committee report make clear that their involvement is critical and that the committee will closely monitor the involvement of local officials in the health planning process.



The Honorable Edward Kennedy  
 March 21, 1979  
 Page 3

In addition, we are proposing that 75 per cent of the members of the governing body of an HSA be appointed directly from outside the HSA. Processes to implement this provision could include direct appointment by various consumer and provider constituency groups or subarea councils.

Finally, there are 12 single state or virtually single state HSAs. In addition, there are several states, such as Iowa and Nebraska, with HSAs of 50 or more counties. In these areas and others, participation by local officials and others is difficult, if not impossible. As a result, we believe that the act should contain a strong endorsement for subarea councils with the indication that where possible, they should follow existing, recognized boundaries. We also believe that the HSAs should be given the authority to delegate elements of plan development and project review authority to the subarea council.

In closing, on behalf of NACo I would like to congratulate you and your staff for the fine job you have done in preparing S. 544. We support many of the provisions already in the bill, including:

- Provisions allowing the Secretary to return agencies which cannot perform to a conditionally designated status;
- Provisions allowing increased rural representation;
- Provisions significantly expanding open meetings and records requirements;
- Requirements for public health and prevention expertise in HSA staffs;
- Provisions making area redesignations easier and requiring consultation with local governments.

We are particularly concerned that adequate funding be provided for the refurbishment of public general hospitals. Many of the large, urban public general hospitals suffer from old and inadequate physical plants which are often in violation of health safety codes.

These amendments will go a long way to remedying the structural and procedural elements which have served to undermine local political support. With these changes, HSAs can become the strong, credible agents for change in the health care system that Congress intended.

If you have any questions on our position, or if we can be of any assistance in securing the rapid passage of this legislation, please do not hesitate to contact me.

Sincerely,



Bernard F. Hillenbrand  
 Executive Director

# **FACTSHEET LEGISLATION**

National Association of Counties

1735 New York Ave., N.W. Washington, D.C. 20006 (202) 785-9577

**Bernard F. Hillenbrand**, Executive Director

## PROPOSED AMENDMENTS TO THE NATIONAL HEALTH PLANNING AND RESOURCES DEVELOPMENT ACT OF 1974

Approved by the Health and Education Steering Committee, March 11, 1979

Proposed Amendments to the National Health Planning  
and Resources Development Act of 1974

The National Association of Counties strongly supports the concept of local health planning. We believe that health systems agencies should be given the authority to limit the growth of unnecessary medical facilities and equipment, to encourage the development of needed medical care facilities and services in underserved areas and, most importantly, to encourage the kinds of public health and prevention activities which we believe have the greatest potentiality for improving health and reducing costs.

However, if local planning and local program development is to be successful, it must occur in an agency which is responsible to the desires of a local community. Free-standing, politically isolated agencies are bound to fail because of their inability to obtain feedback on the status of broad political support for their policies. In spite of the congressional intent to create an open process, the confused and complicated representational requirements in P.L. 93-641 allow a dominant faction in a private, non-profit health systems agency to manipulate appointment process in such a way as to assure control. The result of this process (which has occurred in many, but by no means all, of the private, non-profit HSAs) is isolation, stagnation and eventual upheaval as necessary support groups become alienated from the planning agency.

NACo believes that this process of exclusion has been particularly significant with respect to elected officials. We have encountered many agencies which have permitted them minimal involvement and have been structured to assure that no legitimate influence external to the HSA can be brought to bear on the decision making process.

The planning and regulatory functions associated with HSAs are basically political processes since they define the processes and criteria by which scarce resources are allocated. Being ultimately political in character, the biggest danger which faces HSAs is that they will be simply ignored. Compliance on paper with structural or procedural requirements may well allow an agency to achieve the necessary approvals from HEW. However, such compliance does not build strong political support within the community; rather it undermines it. Such support can only be built upon a process and structure which assures that major interests feel that they are meaningfully represented in the actual decision-making bodies of the HSA. It must also include an aggressive effort on the part of the volunteers and the senior HSA staff to sell their agency -- its processes and policies -- to a broad based constituency. Without broad public support, neither public nor private HSAs will be able to withstand the pressures which will eventually result from policies aimed at making the health care system more efficient and effective.

The result of this isolation will be that, like so many previous ambitious planning activities, the plans and policies of HSAs will prove to be dust collectors on innumerable shelves and decisions of the HSA will soon lack credibility as various avenues of circumvention appear.

The elected local official is one of the only participants in the process who can demonstrate a direct relationship to a constituency; who is accessible to the public through a regularized and well understood process; and who can provide a perspective which is different from the narrowly defined interests and constituency, if any, of most "consumers" and "providers."

Thus, NACo feels that in its review of P.L. 93-641 Congress must more clearly identify realistic goals for the HSAs, must give them the tools necessary to plan for the improvement of health and limitation in the cost of medical care. Most importantly, it must assure that the health planning system is open and that significant interests including elected officials have not only input but impact on local health policy decisions.

## I. Area Redesignations

### A. Criteria for redesignation

#### *Section 1511(b)(4)*

*The Secretary shall review on a continuing basis and at request of any Governor or designated health systems agency or units of general purpose local government the appropriateness of the boundaries of the health service areas established under paragraph (3) and, if he determines that a boundary for a health service area no longer meets the requirements of subsection (a) or if a proposed health service area more appropriately or more completely meets the requirements of subsection (a), he may revise the boundaries in accordance with the procedures prescribed by paragraph (3)(B)(ii) . . .*

Particularly with respect to the west and the south, NACo has found a number of statewide HSAs which are difficult, if not impossible, to administer. In other areas there are also substate regions that may well prove to be inappropriate.

While NACo generally concurs in the belief that the modification of a health service area should be difficult and infrequent, we nevertheless believe that redesignation of areas should not wait until the existing area is in direct violation of Section 1511(a). Rather we feel that when a substantially better area is identified -- one which has the support of the local communities and the governor -- then the Secretary should consider whether the area is more appropriate for health planning than the existing area. If it is more appropriate area, then redesignation should occur.

The provision allowing designation when more appropriate area are identified is similar to provisions in H.R. 11488 and S. 2410 considered by the 95th Congress.

#### B. Procedures for redesignation

##### *Section 1511(b)(4) [new section]*

The Secretary shall issue regulations indicating the criteria for area redesignation. In addition, for each requested area redesignation, the Secretary shall hold a formal hearing and shall issue a written decision in each case.

NACo believes that the criteria for area redesignation should be clear and consistently applied. Regulations have been published containing a statement of criteria 41 F.R. 39433 (1975) .

However, the Bureau of Health Planning's policy in handling requests for area redesignation is to use ad hoc committees with only a set of minutes as the result of that process. The procedure gives no clarification to the criteria listed in the regulations.

NACo believes that the process of making decisions on area redesignations should help to clarify the criteria for redesignation -- not obscure them.

In order to assure that decisions are rational and the criteria applied consistently, the use of ad hoc committees should be eliminated. Rather, there should be a formal hearing. As a result of this hearing, a written record should be developed with a finding of fact, a statement of the relevant statutory and regulatory language and HEW policy; a finding of facts and a decision. Similar provisions were included in S. 2410 and H.R. 11488 considered by the 95th Congress.

#### II. Repeal Section Giving Priority in Area Designation to 314(b) Areas

*Section 1511(c) [gives priority for area designation to areas which have a comprehensive plan prepared under Section 314(b) of Title III of the Public Health Service Act] Repeal.*

This provision effectively excluded most counties and public regional planning bodies from being designated as health systems agencies. This provision, along with Section 1514, which authorizes the provision of technical assistance only to private, non-profit applicants, has done much to create a feeling of animosity toward the legislation by elected county officials. Repeal of this section would help to indicate that Congress now believes that public and private applicants should be given equal assistance and consideration in any future redesignation resulting from the failure to renew the designation agreement of an existing agency or because of area redesignation. Similar provisions were included in S. 2410 and H.R. 11488 considered by the 95th Congress.

### III. Including Public Health and Prevention Expertise as Part of HSA Staff

#### Section 1512(b)(2)(A)

*Expertise -- A health systems agency shall have a staff which provides the agency with at least the following: (i) Administration, (ii) the gathering and analysis of data, (iii) health planning, (iv) development and use of health resources, and (v) public health and prevention of disease.*

Research conducted by the National Association of Counties Research Foundation indicates that many HSAs are focusing almost exclusively on medical care. Health, of course, is not alone affected by medical care. Rather, it is a function of what we eat, drink, breathe and the kinds of life styles we live. It is clear that we will neither improve health or reduce cost as long as HSAs continue the excessive emphasis on health care. Rather, HSAs must take a broader perspective on health and the relation between health and medical care.

Therefore, NACo believe that Congress should also reaffirm its intent that HEW assure that approved Health Systems Plans contain aggressive and realistic goals in the area of public health and prevention. Similar provisions were included in H.R. 11488 and S.2410.

### IV. Public Health Systems Agencies (Powers of the Governing Board)

#### Section 1512(b)(3)(A)

*In general, a health systems agency which is a public regional planning body or unit of general local government shall, in addition to any other governing body, have a governing body for health planning, which is established in accordance with subparagraph (C), which ~~shall~~ may have the responsibilities prescribed by subparagraph (B), and which has authority to perform for the agency the functions described in section 1513. The elected governing body of any unit of local government or regional planning unit which is a health systems agency shall have exclusive authority to:*

- i) Establish personnel and other rules and regulations for the operation of the agency.*
- ii) Review and approve or return to the Governing Body for Health Planning for revisions the Health Systems Plan and Annual Implementation Plan.*
- iii) Review and approve or return to the Governing Body for Health Planning for revisions criteria required pursuant to Section 1532 [project, institutional and appropriateness reviews].*

iv) Review and approve or disapprove the agency's budget.

Section 1512(b)(3)(C)

A public regional planning body or unit of general local government which is a health systems agency may appoint the members of its governing body for health planning.

The Secretary, in developing the regulations for health systems agencies, commented that "the relationship between these two bodies (the governing board and the governing body for health planning) has been one of the more controversial aspects of the implementation of P.L. 93-641." The Moss Amendment to P.L. 93-641 Section 1513(b)(1) was added to allow units of local government and public regional planning bodies to function as health systems agencies. Floor colloquies indicated that the governing body of the unit of local government or public regional planning body which was an HSA (i.e. the governing board) should have the authority to set rules and regulations for the HSA, approve the annual budget, review and approve the health system plan and annual implementation plan, and appoint and remove members of the governing body for health planning.

However, under the present regulations the governing board has little function except to appoint the members of the governing body for health planning. After appointment, however, the governing body for health planning is totally independent. As a result, the governing body for health planning is not accountable to the governing board.

These proposals follow the interpretation of Judge Kaufman in the case of Montgomery County vs. Califano (Civil #K77-166 mimeo). In that case, the court ruled that the Secretary had exceeded his discretion and violated the intent of Section 1512 (b)(3)(A) by ruling that the governing board had only the authority to appoint the governing body for health planning and to establish the agency's rules and regulations.

Our proposal is based on the proposition that the city/county regional planning body should have the authority to establish the overall structure of the agency and approve or revise, with the participation of the governing body for health planning, the major policy documents of the HSA.

In proposing that these authorities be ultimately vested with the Governing Board, we are not proposing that each city, county, regional planning body, joint powers agency or special district should exercise all authorities. However, we do strongly believe that these bodies should have the authority to decide which powers they wish to exercise themselves and which they wish to delegate to the governing body for health planning. This provision closely parallels the language in H.R. 11488.

**V. Increased Involvement of Elected Local Officials on Private, Non-Profit HSAs**

## Section 1512(b)(3)(C)(iii)(I)

(iii) the membership shall--

- (I) include (either through consumer or provider members) public elected officials and ~~other representatives of governmental authorities~~ or other representatives of units of general purpose local government in the agency's health service area and representatives of public and private agencies in the area concerned with health. To be considered as a representative of general purpose local government on the governing body and executive committee (if any), the elected official or other individual must be appointed by a unit of general purpose local government or combination thereof. For the purpose of this clause, the State government or a state which contains a single health service area shall be deemed to be a unit of general purpose local government.

One of the most vocal concerns expressed by county officials with whom we have had contact has been the failure to obtain direct representation on HSA governing bodies for health planning. Often local elected officials or other governmental representatives constitute a small percentage of the governing body. Persons designated as "representatives of local government" have been appointed without the knowledge or consent of local government. The problem, of course, is one of definition and extends well beyond elected officials. Simply stated, it is clear that because an individual is a member of a group -- local elected officials, physicians, hispanics, etc. -- that individual has no inherently legitimate claim to represent that category. It is clear that the Congressional intent was to represent local government on the HSA governing body and the executive committee. However, the notion of "representation" has been lost in the implementation of the Act. Most HSAs have fallen into the practice of calling elected officials (and others) "representatives" of a group or groups merely because they are members of the group. Thus, an HSA, with HEW's blessing, will consider a black female elected official as a representative of blacks, women and the local governmental unit to which she was elected.

This tendency is quite understandable given the difficult if not impossible composition requirements for the governing body for health planning in P.L. 93-641. However, the result of this practice has been virtually to eliminate the possibility that local government and other interests have legitimate and responsible representatives on the governing body.

Many HSAs employ a system which insures that the existing governing body of a private, non-profit HSA, or a subcommittee of it, has final authority over membership. This is not accountability. Accountability, outside of election,



can only come through the direct appointment of (and authority to remove) "representatives" who will represent the interests of a constituency. It is only through this method that external interests can have impact on the HSA governing body structure and the policies of the HSA.

NACo believes that elected officials representing general purpose local government must have increased participation in private, non-profit HSAs. Local elected officials are politically responsible. Planning is basically a political activity since it acts to identify needs, define those needs in the context of scientific findings and allocate scarce resources to each need. If this political process is to have legitimacy and, more importantly, receive necessary feedback from those unorganized and less articulate members of the community, then increased local elected officials involvement is crucial.

We, therefore, believe that Congress should assure that those individuals identified as "representatives of local government" are in fact the representatives of the policy making branch or branches of local government and not merely employees of a city or a county. The proposed changes would assure that those designated representatives of local government are designated by a city or county.

#### VI. Powers of the Executive Committee

##### *Section 1512(b)(3)(A)*

*...Any other health systems agency shall have a governing body composed, in accordance with subparagraph (C), of not less than ten members and of not more than thirty members, except that the number of members may exceed thirty if the governing body has established another unit (referred to in this paragraph as an "executive committee") composed, in accordance with subparagraph (C), of not more than twenty-five members of the governing body and has delegated. The governing body may delegate to that unit the authority to take such action (other than the establishment and revision of the plans referred to in subparagraph (B)(ii)) as the governing body is authorized to take.*

Under the present law, a governing body for health planning must delegate all authorities (other than to establish and review the HSP and AIP) to the executive committee. As a result, for such activities as project review, 1122 and certificate of need review and appropriateness review, the executive committee becomes, under this legislation, the equal of the full governing body rather than its subordinate.

NACo believes that it is advisable to keep the size of the governing body below 30. However, if a larger governing board is required, then we believe that the powers of the executive committee should be set by the governing body itself and not by Congressional mandate.

## VII. Rural Representation

*Section 1512(b)(3)(c)(iii)(II)*

*Include at least a percentage of individuals who reside in non-metropolitan areas within the health service area which percentage is at least equal to the percentage of the area.*

Congress in its final deliberations on P.L. 93-641 became concerned that rural areas would be under-represented on HSA governing boards and bodies. In order to avoid this problem and to insure participation by rural areas, Section 1512(b)(3)(c)(iii)(II) was added. However, rather than acting as a floor for participation by rural interests, this provision has placed a cap on their involvement.

Local areas must develop a means of accommodating non-urban interests when there is a large metropolitan county surrounded by rural areas. Often, these accommodations may over-represent rural areas, yet are satisfactory to both rural and urban counties. In fact, in mixed areas the urban representatives predominate even when rural interests are over represented.

There is often a strong push in the HSA to have at least one representative from each county. This pattern is often used in other areawide agencies. The effect of this effort, coupled with the "equal to" provision, results in huge governing bodies. Any attempt to limit the governing body for health planning to a reasonable size results in a denial of membership to some rural areas. More importantly, it represents yet another point of friction between rural and urban areas and can disrupt the development of the HSA.

NACo believes that a review of the background of the "equal to" provision would indicate that the Congressional intent was to create a floor to encourage rural participation.

Therefore, we propose to amend the "equal to" provision to read that, at a minimum, the urbanized/non-urbanized mix should equal that of the area. However, we also believe that any rural representation beyond the minimum must represent the consensus of both the urban and rural areas.

## VIII. Open Meetings and Records

*Section 1512(b)(3)(B)(viii)(I-III)*

I) Except for confidential meetings called to discuss the performance or remuneration of individual HSA employees, all meetings of the HSA governing body or executive committee, and any subarea council, committee or subcommittee meetings must be open to the public and held with full notice to the public of such meetings,  
II) adequate public notice of meetings must be provided, including dissemination through newspapers, radio, television and mailing

lists of interested individuals, III) all records, excluding only personnel records and data on individual staff members, must be open to the public and available upon request.

HSAs, be they public or private, perform functions which are essentially public in nature. The public's business should be conducted in the public eye. Sometimes, the eye needs to be propped open. When the public does not show interest or care to participate in HSA activities, this often means that it has not been adequately informed about those activities. HSAs have a responsibility to keep their public informed.

The process which NACo proposes for the public review of agency designation applications, HSPs and AIPs covers only a few key HSA functions. Even so, we suggest only the most skeletal elements required for accountable public review in that process. In a more far reaching sense, the public -- including the representatives who are elected to govern in the public's behalf -- also needs to be involved in the routine activities of the agency. This requires that special efforts be made to assure that ordinary private citizens, public officials, and individuals and groups who can reasonably be presumed to have a special interest in any particular activity feel that this activity is accessible to their participation.

HSAs are required to meet on a regular basis and to advertise their meetings. We have found, though, that the meeting schedule is sometimes irregular and that the advertisements consist of ads in the legal notices sections of newspapers. In addition, meetings are often held in places which are too small to accommodate an audience, or at inconvenient times or locations. Moreover, opportunities for the public to address these meetings tend to be very carefully limited and controlled.

We believe that this provision must be strengthened because examples which have come to our attention of violations of the intent of the current provision. NACo has had county officials tell us of applicants being excluded from project review meetings at which their proposal was discussed.

Therefore, in this provision we propose to require the HSA to undertake an active program to inform the citizen of the activities of the agency. These would include broad publication of all HSA meetings, use of mailing list of interested individuals, use of many meeting sites in large HSAs, etc. We would also propose that Congress specifically indicate its intent that HSAs comply with state "Government in the Sunshine" laws.

## IX. Prohibition of Self Perpetuating HSA Governing Bodies

### *Section 1512(b)(3)(D)*

(D) Selection -- Each Health Systems Agency shall establish a process for the selection of members of the governing body which process is designed to assure that (i) such members are

selected in accordance with the requirements of subparagraph (C) [Composition requirements of HSA Boards] , (ii) there is the opportunity for broad participation in such process by the residents of the Health Service Area, and (iii) that nomination and selection of at least 75 per cent of the consumer membership and 75 per cent of the provider membership of the governing body will not be made by the governing body.

The verb "to represent" has two main definitions given by Websters. One is "to serve as a sign or symbol." The second is to stand or act ". . . For another especially through delegated authority." These two quite separate usages of the word represent have been consistently confused in the implementation of P.L. 93-641, and the confusion lies at the heart of the protests, suites, and ongoing revisions of instructions to HSAs on composition requirements for HSA governing bodies.

NACo has commented previously on the appointment process because we have found that substantial problems exist relative to how individuals are appointed to HSA governing bodies. The problem is, simply, that all too often a small, select board or committee of the HSA chooses people to sit on HSA bodies who they feel represents the interest of consumers or various interest groups within the consumer category. In addition, as we noted in our report to BHPRD, Health Planning Under P.L. 93-641: Making It Work:

Our site visits have indicated that. . . many HSAs have fallen into the practices of calling any member of a group on an HSA governing body a "representative" of that group. This tendency is quite understandable given the difficult, if not impossible, composition requirements of the governing body specified in P.L. 93-641. However, the result of this practice has been virtually to eliminate the possibility that local government and other interests have legitimate, responsible representatives on the governing body.

We believe that each member of the governing body must show a "constituency relationship" between themselves and the group or groups they purport to represent. Being a member of a group by itself is clearly insufficient. The most critical element is that the individual or individuals are selected by a broad base of interest groups who have a recognized role as an advocate or service provider to "social, economic, linguistic and racial populations" or through the use of subarea councils to appoint members from various geographic regions within the HSA. Other criteria might include individuals with a special knowledge of minority health problems or individual leaders in the minority community.

The proposed requirement, which is similar to provisions in H.R. 11488 and S. 2410 in the 95th Congress would force HSAs to utilize outside organizations and processes to obtain appointments to HSA governing bodies.

#### X. Area Health Services Development Fund

## Section 1513(c)(3)

*(3) The Agency shall, in accordance with the priorities established in the AIP, ~~make grants to public and non-profit private entities and enter into contracts with~~ solicit proposals from individuals and public and non-profit private entities to assist them in planning and developing projects and programs which the agency determines are necessary for the achievement of the health systems described in the HSP. The proposals shall be submitted with the agency's review and recommendations to the state health planning and development agency.*

NACo believes that distribution of funds is an inappropriate function for regional bodies, particularly one which is, to date, so far removed from local government. The American County Platform states that regional bodies shall not allocate funds.

This policy is based on our strong belief that the final allocation of tax monies is one of the most politically sensitive functions of government. The allocation of these funds is not a function of any regional or multi-jurisdictional entity -- no matter how many elected officials participate. This function must remain with federal, state or local government and, in this case, we believe it should be a state function.

Therefore, the amendment of this section would place a review and comment function in the HSA with a final funding decision lodged with the state.

## XI. Relations Between HSAs and Units of Local Government

## Section 1513(e) [new section]

Each health system agency shall enter into formal written agreements with units of general purpose local government or, in large HSAs, with existing combinations of units of governments. Such agreements shall include:

- a) the number of appointments and the process for making direct appointments to the governing body for health planning.
- b) the method and schedule for review by the local government or combination thereof, of the HSP, the AIP, the agency's application for refunding and other appropriate policy documents.
- c) the process by which suggested changes will be included in review documents and how disputes between the HSA and units of local government will be resolved.

Under the present legislation, HSAs can function without the meaningful involvement of local government. The HSA can be established so as to virtually exclude the meaningful impact of the views of elected officials. Self selection of governing body members can virtually isolate the HSA from any local impact through its governing body selection process. In addition, A-95 reviews generally are ignored with impunity.

Elected county officials are critical participants in the planning and implementation process. Local governments:

- Provide most of the public health and environmental health activities in a community;
- Provide care to the medically indigent;
- In 18 metropolitan states share in the costs of Medicaid;
- Often must fund new programs when federal seed money expires and third party payments are either unavailable or insufficient;
- Provide mental health, mental retardation, alcoholism, and drug treatment and services.

In order to increase the involvement and impact of local officials, we propose that HSAs be required to establish formal written agreements with units of local government. Where there are a large number of municipalities and counties in a health service area, we believe that area redesignation should be considered.

However, in areas with sparse population, we believe that formal agreements with regional planning bodies, councils of government or other regional units and the major units of local government is an acceptable substitute.

NACo believes that it is critical that a formal and binding agreement exist between local government and HSAs. It is only through procedures such as these that any guarantee of continued HSA accountability can be assured.

XII. Provision for Return to Conditional Designation for Non Performing Agency.  
[New section]

If upon review (as provided in Section 1535) of the Agency's operation and performance of its functions, the Secretary determines that it has not fulfilled in a satisfactory manner the functions of a health system agency as prescribed by Section 1513 during the period of the agreement to be renewed or does not continue to meet the requirements of Section 1512(b), he may terminate such agreement or return such agency to a conditionally designated status under subsection (b) for a period not to exceed 12 months. At the end of such period, the Secretary shall either terminate its agreement with such agency or enter into an agreement with such agency under paragraph (1) [full designation agreement].

NACo believes that the sanctions open to the Secretary should provide more options than the extreme option of new renewing the designation agreement. Generally speaking, political pressures will limit the use of such severe sanctions. As a result, there is virtually no way in which the Secretary can force good faith compliance with the requirements of Section 1512 and the improvements in functions carried out under Section 1513.

The proposed amendment would allow the Secretary to impose the restrictions and additional control of conditional status on agencies which fail to implement in good faith Section 1512 and 1513. It provides a middle ground and avoids the extreme of totally eliminating, over a short time, the planning function within an area. If at the end of the 12 month-period the agency is still unable to perform, it can be terminated by the Secretary. The proposed language is that adopted by the Senate in S. 2410.

### XIII. Technical Assistance for Health Systems Agencies and State Health Planning and Development Agencies

#### *Section 1533(a)*

*The Secretary shall provide (directly or through grants or contracts or both) to designated health systems agencies and State Agencies (1) assistance in developing their health plans and approaches to planning various types of health services, (2) technical materials, including methodologies, policies, and standards appropriate for use in health planning, (3) programs to provide training to the members of the governing bodies and governing boards of health systems agencies and state health coordinating councils, and (4) other technical assistance as may be necessary in order that such agencies may properly perform their functions.*

Congress, in the passage of P.L. 93-641, opted for a system of planning and regulation in the health field that focused on broad participation by all segments of the community. If this broad participation is to be effective, there must be strong support for consumer and many provider on SHCCs and HSAs. The interests of the many groups which are represented are far from self evident given the technical complexity of the health planning process and the volume of materials which must be digested by board members. If training is not made available on the basic issues and options in health care, then many representatives will fall under the control of provider or other interest.

This amendment would mandate that the Secretary, as part of his overall technical assistance program, provide training to consumer and provider members of HSA governing boards and bodies and to SHCC council members. In addition to providing information on the legislation and structural and procedural issues within the HSA, training should focus on:

- a) Disease prevention

- b) Public and environmental health
- c) The impact of these practices on utilization and long term cost control
- d) Short term cost control measures
- e) Factors contributing to excessive and inappropriate medical procedures and facility utilization

#### XIV. HSA Budget Review by the Secretary

##### *Section 1535(a)*

*The Secretary shall review and approve or disapprove the annual budget of each designated health systems agency and State Agency. In making such review and approval or disapproval the Secretary shall consider the comments of Statewide Health Coordinating Councils submitted under section 1524(c)(3) and the comments of units of general purpose local government within the health service area.*

NACo feels that the A-95 review function has been marginally effective, at best. Counties tell us that HSAs as well as HEW ignore their comments with impunity. NACo believes that in the face of this ineffectiveness, P.L. 93-641 should be amended to insure that it contains adequate provisions for review of local governmental comments by the Secretary. In line with this overall policy, we believe that Section 1535(a) should be amended to require that the Secretary to consider the comments of local government in his review of HSA budgets.

#### XV. Funds for Renovation of Public General Hospitals

##### *Section 1613*

*Except as provided in section 1625(d), there are authorized to be appropriated for allotments under section 1510 \$140,000,000 for the fiscal year ending September 30, 1980, \$145,000,000 for the fiscal year ending September 30, 1981 and \$150,000,000 for the fiscal year ending September 30, 1982.*

##### *Section 1625(a)*

*[Project grants for upgrading public medical facilities] (d) of the sums appropriated under section 1613 for a fiscal year, there shall be made available under subsection (a) for such fiscal year 50 percentum of such funds.*



Three out of ten hospitals in this country are owned by state or local government. Often these hospitals provide access to care for those who are unable to utilize private facilities due to geographic or social barriers. In the large urban area the public general hospital (often county) has had the historic function of serving the poor. In some states the county is mandated to provide this service. In rural areas, the public general hospital often provides exclusive service. In fact, over 40 per cent of all rural hospitals are publicly operated.

In addition to their different clientele, the public general hospital also provides a somewhat different array of services. Often, they are the only hospital to willingly accept alcoholism and drug abuse cases. A recent study of large urban hospitals also indicated that they provide three times more outpatient services relative to their inpatient workload than the average community hospital of comparable size. In the rural areas, they are a major source of primary care.

This mix of services has caused serious financial problems for the public general hospital. The patient in urban public general hospitals are the most poor and most seriously ill. Third party payment often fails to meet expenses, and the local governmental tax base provides the resources to fill this gap. Rural public and other general hospitals suffer from third party payment rates which are lower than urban rates.

The financial problems of local government makes it difficult to raise capital for reconstruction or renovation of the public general hospital. Tax revenues cannot meet their need, and localities often must borrow at extremely high interest rates. In some cases, localities are excluded from the bond market altogether. Often the physical plant is old and renovated only with extreme difficulty, yet renovation is required if the hospital is to meet life safety codes. Public funds deriving from sources other than the property tax is critical to the upgrading of the public general hospital.

Finally, it is often noted that there are an excessive number of beds, primarily concentrated in the urban areas. NACo agrees with this finding and supports strong controls on construction and renovation. However, the services provided by the public institutions are unique in that they serve a clientele which cannot obtain services elsewhere and provide services, such as alcohol, drug abuse and mental health, which are often not provided by other facilities. We believe that as a result of these differences, generalizations on bed limitations do not necessarily apply to publically operated institutions. We believe that the review of proposed renovation or construction of public general hospital beds or other facilities should take into account the specialized services of the institution. If the proposed construction is needed, then federal funds should be available to finance it.

In addition to the above specific proposals, the National Association of Counties urges Congress to pass the following provisions:

- a) To provide financial assistance for the voluntary closing of unneeded hospital services and the conversion of hospital services;
- b) To require the approval of the Governor of the State Health Plan;



**National  
Conference  
of State  
Legislatures**

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President  
Jason Boe  
President of  
The Oregon Senate  
  
Executive Director  
Earl S. Mackey

March 20, 1979

The Honorable Edward Kennedy  
Chairman, Senate Human Resources  
Subcommittee on Health and Scientific Research  
431 Russell Senate Office Building  
United States Senate  
Washington, D.C. 20510

Dear Mr. Chairman:

As the Senate Subcommittee on Health begins its consideration of the reauthorization of the National Health Planning and Resources Development Act (PL 93-641), I hope you will consider the concerns and suggestions expressed by the nation's state legislatures with respect to that law. The National Conference of State Legislatures very much supports the goals and purposes of the Health Planning Act and believes that, for the most part, the Senate Subcommittee bill would go a long way toward ensuring that those original goals are fulfilled.

Given the range and depth of state governmental involvement in the health care system, and the need for greater coordination among the various components in that system, we are hopeful that the subcommittee's policy will be one of supporting a stronger state role at the center of the health planning system.

The major thrust of our recommendations relate to improving the structure and responsibilities created by the federal statute, especially the functions and relationships between the local planning bodies (HSAs) and the statewide health coordinating councils (SHCCs), and the established state and local government authorities.

We believe that the modifications we seek will contribute toward improving the performance of these bodies and ensure overall accountability.

The specific recommendations of the NCSL are as follows:

1. Permit the Governor, with the advice and consent of the State Senate, to appoint the chairman of the SHCC;
2. Provide authority to the Governor, in consultation with the appropriate state legislative committees, to approve the state health plan and subsequent revisions to it;
3. Provide for increased involvement of public elected officials on the governing bodies of the health systems agencies; and
4. Expand federal financial assistance to States that are interested in experimenting with hospital rate review and rate setting.

Page Two

Finally, I would like to draw your attention to one element in last year's legislation which our organization specifically objects to. The language would change the law to read: "each certificate of need in the State that is issued must be based solely on the record established in administrative and judicial proceedings held with respect to an application for such certificate in order for such certificate of need program to be in compliance." The report language suggested that this amendment is needed to check the practice in some States in which the state legislature enacts state legislation directing the State Agency to approve specific projects.

We have three principal concerns with this amendment. First, there has not been a widespread practice on the part of state legislatures in overriding State Agency decisions on certificate of need. In fact, since the inception of PL 93-641 there are only two incidents wherein a legislature exempted a particular hospital from the certificate of need process, and in one of those situations, the exemption was declared unconstitutional by the State Supreme Court. Hence, we feel it is a bad precedent to establish national policy based solely upon two exceptional occurrences. Secondly, and relatedly, most States have laws which prohibit special exception or special treatment legislation. Thirdly, the amendment is an affront to the large majority of state legislative bodies that have enacted certificate of need programs and are working hard to ensure that they operate effectively and in accordance with legislative intent. Such an amendment could effectively undermine the general goodwill and cooperative relations that have existed between the legislatures, the Congress and the Department of HEW in pursuit of common health planning and resources development objectives.

Thank you very much for your consideration.

Sincerely,

*Mary Marshall*

Mary Marshall  
Chairperson, Human Resources  
Committee of NCSL  
Delegate Commonwealth of Virginia

*John Bragg*

John Bragg  
Chairman, State-Federal  
Assembly of NCSL  
Chairman, Tennessee House Finance,  
Ways and Means Committee



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

180 N. LaSalle St.  
SUITE 1521  
CHICAGO, ILLINOIS 60601  
(312) 744-6696

April 19, 1979

Senator Edward M. Kennedy  
Chairman  
Subcommittee on Health and  
Scientific Research  
431 Russell Senate Office Bldg.  
Washington, D.C. 20510

Dear Senator Kennedy:

The National Council on Health Planning and Development, established under P.L. 93-641 as an advisory body to the Secretary of the Department of Health, Education, and Welfare, wishes to express its concern regarding the continued and appropriate funding of the national health planning process and structure.

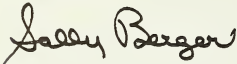
The national health planning program, which began only three short years ago, is beginning to show some very tangible and positive results of its actions. We urge that a bill to extend the Planning Act be acted upon as soon as possible so we may continue to fulfill the mandate you set for us in this Act.

Additionally, we urge, that in your deliberations, you clarify the issue of immunity from anti-trust actions resulting from resource allocation decisions made by or at the request of Health Systems Agencies (HSA's).

Senator Edward M. Kennedy  
April 19, 1979  
Page Two

If the National Council can be of any assistance to you or your Committee in this process, please do not hesitate to contact me.

Sincerely,



Sally Berger, Chairman  
National Council on Health  
Planning and Development

SB:rms

cc: All National Council Members  
Henry Foley, Ph.D., Administrator  
Health Resources Administration  
Colin Rorrie, Ph.D., Director  
Bureau of Health Planning  
Florence Fiori, Dr. P.H., Director  
Bureau of Health Facilities  
Financing, Compliance & Conversion  
S. Judy Silsbee, Executive Secretary  
National Council on Health Planning  
& Development

PSCOG

Grand Central on the Park • 216 First Avenue South • Seattle, Wash. 98104 • 206/464-7090

Puget Sound Council of Governments

March 20, 1979

The Honorable Edward M. Kennedy  
 The United States Senate  
 Russell Senate Office Building  
 Washington, D. C. 20510

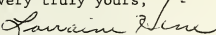
Dear Senator Kennedy:

As you know, Section 1531 of the National Health Planning and Resources Development Act, P.L. 93-641, defines as an indirect provider the spouse or a member of the immediate family of a direct provider.

The Puget Sound Council of Governments has become very active in health planning matters in recent years in cooperation with our local Health Systems Agency. Our increasing awareness of the provisions of P.L. 93-641 convinces us that the rule classifying a person as a provider because their spouse is one has an unfortunate discriminatory effect. While it may not have been intended, the rule results in many persons being disqualified from participating in health matters because their husbands or wives are doctors or other direct providers. Today, perhaps more than ever before, people are of independent mind and ought not be classified in terms of their spouses' outlook on health or other public policy issues.

Because of your national stature in health matters and your chairmanship of the Subcommittee on Health and Scientific Research, I draw your attention to this matter so that you might introduce an amendment to the Act to correct this basic unfairness to people all over America who are able and anxious to participate in shaping our health policies but who are prevented from doing so by the accident of their marital status.

Thank you for your interest and support.

Very truly yours,  
  
 Lorraine Hine, President  
 Mayor, City of Des Moines



**SEIU**

**Committee on Political Education**  
Service Employees International Union, AFL-CIO/CLC  
2020 K Street, N.W., Washington, D.C. 20006  
George Hardy, International President  
Anthony G. Weinlein, International Secretary-Treasurer  
Richard E. Murphy, COPE and Legislative Director  
(202) 452-8750

Statement  
of the  
Service Employees International Union, AFL-CIO  
Before the  
Subcommittee on Health and Scientific Research  
Senate Committee on Human Resources  
Hearings on the Health Planning Amendments of 1979  
to the Public Health Service Act  
S. 544  
April 3, 1979



The following statement represents the views of George Hardy, president of the Service Employees International Union which represents over 600,000 workers in public and private employment, including over 225,000 healthcare workers.

Health planning, as established in Public Law 94-641, supplies an orderly rational approach to health resource allocation but the interim period since enactment of the planning law has not been problem-free. S. 544 attempts to resolve some of these shortcomings and omissions. However, we feel that the proposed health planning amendments of 1979 could be greatly strengthened in several key areas.

Our most immediate concern is with the proposed Part G of Title XVI which seeks to assist and encourage the discontinuance of unneeded hospital services. As long as efficient utilization of all healthcare resources is the primary aim of the planning process, we feel that wasting healthcare manpower resources is incompatible with proper health planning.

We greatly appreciate the fact that Sec. 1643 has been strengthened this year to provide for proper consideration of the possible deleterious effects of closures and cutbacks on healthcare workers. We fully support Sec. 1643 (e) which requires certification of cutback plans by the Secretary of Labor to insure that fair and equitable arrangements have been made to protect the interests of employees including reassignment to

other jobs, retraining programs, maintenance of pension and health benefits and protecting collective bargaining rights. We feel that Sec. 1643 (e) correctly recognizes that effective manpower planning in the healthcare industry means, not only stimulating the supply of trained personnel when shortages exist, but also means dealing responsibly with dislocations and temporary maldistribution problems when they occur.

Effective health manpower planning should be consistent with overall employment strategies developed for the economy. Sec. 1643 (e) would go a long way toward bringing health planning legislation into conformance with national employment goals and provide coordination of purpose with federal manpower policy efforts.

We would go farther in urging the addition of another type of incentive payment which would be earmarked for handling potential unemployment problems.

Part G of Title XVI should be appropriately amended to establish an incentive payment to other hospitals in the health service area which are willing to accept displaced hospital workers in their facilities. This should be a reasonable incentive structure that coupled with a strict attrition program would, within a reasonable period of time, return the hiring institution to appropriate levels of staff. (Tying the incentive payment structure to a strict attrition program would prevent permanent overstaffing). Furthermore, where immediate placement in other facilities in the area is impossible, these

incentive payments should be expended for retraining and assisting displaced workers secure other suitable employment. These proposals would not totally remove the negative employment effects of discontinuing hospital services but would represent a positive program for efficient utilization of health manpower within the context of national employment goals.

With respect to other portions of the bill, we heartily support the additional staff requirements listed in Sec. 105 for health systems agencies, to assure expertise in financial and economic analysis and public health and disease prevention. The full potential of HSAs as planning instruments can only be realized if proper analysis of the economic impact of various healthcare decisions is carried out and if HSAs concentrate on plans for improving the "wellness" of the members of their respective communities instead of merely looking at resources for dealing with illness. We are particularly pleased that S. 544 makes some effort to supply consumer members of HSA boards with research assistance to help analyze technical documents and evaluate alternatives.

In addition, Sec. 149 (c) which would require that Centers for Health Planning develop and disseminate methodologies to educate new board members and staff, represents an improvement over the current level of educational effort. However, we would strongly suggest that such educational initiatives be primarily devoted toward upgrading the consumer members of HSAs who are often frustrated by the technical jargon used by providers and staff.

Greater involvement in health planning by major health-care purchasers such as labor unions and corporations needs to be encouraged in order that planning agencies may benefit from the expertise and experience of such groups. Recognition of labor unions and corporations as major purchasers of health-care in Sec. 110 should prove helpful toward that end. Additional labor and management health planning input is likely to be gained through the Sec. 141 (b) proposal to allow consumers who serve on boards of other health organizations and agencies to be considered as consumers, rather than indirect providers. Many knowledgeable labor and management representatives currently fall into this category.

We believe that Sec. 113 which amends Sec. 1512 (b) (3) (c) (ii) to explicitly include nonprofessional health workers as provider members of the HSA governing body is long overdue. It is about time that a group that represents a majority of the healthcare industry labor force had a voice in planning health-care delivery.

At the same time we feel that consumers should constitute at least 60 percent of the membership of an HSA governing body. We recommend amending Sec. 1512 (b) (3) (c) appropriately.

Inasmuch as P.L. 93-641 lists the development of HMOs as among the top national health priorities, we believe that HMOs should be evaluated within a specially developed HMO frame of reference. Therefore, we support the intent of S. 544 to promote HMOs, and, further, endorse the establishment of a requirement

that would prevent HMOs from being discriminated against in State certificate of need programs. Hospital based HMOs as a group have demonstrated substantial economies compared to the fee-for-service sector. HMOs encourage efficiency and eliminate waste in healthcare delivery, thereby moderating the rise in healthcare costs. It makes good economic sense to promote their development. Artificial obstacles placed in the path of HMOs by the healthcare establishment in certain communities through their dominance of the planning process should be removed.

Finally, we strongly support amending the planning law to broaden State certificate of need requirements to include expensive equipment with a value over \$100,000 regardless of location except when such equipment is utilized exclusively for patients of health maintenance organizations. This would close the loophole by which private physicians have installed in their offices expensive diagnostic or therapeutic equipment, such as "CAT" scanners, which unnecessarily duplicate equipment already available in the community. Healthcare costs have been unnecessarily pushed up by the increasing price and proliferation of new technology. The amendment we propose will be of great benefit in discouraging circumvention of the health planning process.

We thank the committee for the opportunity to present our views on the proposed health planning amendments of 1979 and we strongly urge you to consider our recommendations for strengthening the proposed legislation.



## Washington Business Group on Health

March 19, 1979

Senator Edward M. Kennedy  
Chairman  
Subcommittee on Health and  
Scientific Research  
Room 310B  
Senate Courts Annex  
Washington, DC 20510

Dear Senator Kennedy:

I am writing to express the support of our organization for S.544, the Health Planning Amendments of 1979.

As you may recall, last year we appeared before your committee to speak on behalf of S.2410. Now, 14 months later, our support for the continuation and improvement of the planning system has been increased.

Our reason for this growing commitment is simple: we have seen that the system can work. That is not to say that it now works well in every location or may ever do so. However, it is to say that, in a remarkably short period, a process has been developed which is, increasingly, demonstrating the capacity to impose a new rigor and professionalism on resource allocation decisions. Perhaps even more important, the HSAs are increasingly the focal point of a new community-wide examination of local health needs.

Business support for health planning could easily be misunderstood. We are not giving a blanket endorsement to a regulatory approach. One of the virtues of the P.L.93-641 design is its local flexibility. For the long-term future of the U.S. health delivery system we believe a balance must be struck between the resource allocation system and free competition among the broadest range of providers for those resources. Not every community will achieve the desired balance simultaneously or with equal effectiveness. The Congress and Administration, we respectfully submit, must be open to varying rates of progress, to opportunities for experimentation and innovation.

A few specific comments on S.544:

1. we applaud your inclusion of "mental health resources" throughout the bill
2. we endorse the consumer member assistance in Sec. 109(a)
3. we are very pleased to see the contribution and participation of both corporations and unions recognized in Sec. 110.
4. Sec. 115: agree that all subcommittees should have a consumer majority

605 Pennsylvania Avenue, S.E., Washington, D.C. 20003 (202) 547-6700

Senator Edward M. Kennedy

March 19, 1979

5. Sec. 123: the inclusion of "cost effectiveness" is endorsed.
6. S.132: while supportive of the intent of this section to speed the state agency designation process, we are concerned that, in some areas, those opposed to planning and federal funding for health care may simply use the proposed sanction process to lessen their delivery system. While, on the surface this seems improbable, the Medicaid experience is painfully illustrative.
7. Sec. 135(7): has the cost of this technical assistance been established and could this not be used as an appeal/delay factor by those whose proposed projects are rejected? i.e.: "we did not receive proper federal assistance".
8. the increased standing provided HMOs is good. If alternative delivery mechanisms are ever to prove cost and quality effective, they must have the opportunity to be initiated.
9. the amendments to Sec. 1523 to provide some control over the use of high cost equipment outside the in-patient setting are endorsed...but only should stronger measures such as those proposed in Sec. 141 of S.2410 not be an acceptable alternative.
10. Sec. 1641: this is certainly needed but to be effective we would note that the Congress and Administration will have to face the anti-trust issues this section raises. It is simply not reasonable to ask each HSA and individual hospitals to follow the guidance of HEW and this Section to risk near certain attack from other government agencies and the courts.
11. Sec. 1642: we endorse the incentive payment system.

I hope these brief comments are of use and that you will convey our support for S.544 to such other Members as may be interested. If we can be of further help, please call.

Sincerely yours,

  
Willis B. Goldbeck  
Director

WBG/jlc

cc: Secretary Joseph Califano



State of Wisconsin \ DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH  
MAIL ADDRESS: P. O. BOX 309  
MADISON, WISCONSIN 53701

IN REPLY PLEASE REFER TO:

MEMORANDUM

DATE: March 19, 1979

TO: Edward Kennedy, Chairman

FROM: Robert Durkin *RD*  
Administrator

SUBJECT: Legislative Changes in P.L. 93-641 Regarding Appropriateness Review

Sections 1513 and 1523 of P.L. 93-641 excerpted below, mandate the development of an Appropriateness Review (AR) Program to be performed by HSAs and SHPDAs.

Section 1513(g)(1): "Except as provided in paragraph (2), each health systems agency shall review on a periodic basis (but at least every five years) all institutional health services offered in the health service area of the agency and shall make recommendations to the State health planning and development agency designated under section 1521 for each State in which the health systems agency's health service area is located respecting the appropriateness in the area of such services.

(2): A health systems agency shall complete its initial review of existing institutional health services within three years after the date of the agency's designation under section 1515(c)."

Section 1523(b)(3): "A State Agency shall complete its findings with respect to the appropriateness of any existing institutional health service within one year after the date a health systems agency has made its recommendation under section 1513 (g) with respect to the appropriateness of the service."

To date, only proposed regulations have been issued by DHEW regarding the administration of this function. Unfortunately, these regulations give little further guidance and direction to those who must implement and administer this major activity. Furthermore, based on the mandate expressed in P.L. 93-641 and the proposed regulations (42 CFR 123.600), I anticipate a number of problems occurring in Wisconsin and the rest of the nation.



Memorandum

March 19, 1979

Page Two

First, the resources currently available to most Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs), including those in Wisconsin, are not sufficient for developing and implementing an AR Program. Several aspects of the law and proposed regulations have the potential for creating undesirable consequences. The federal requirement that reviews of "all existing institutional health services" be completed by HSAs within three years of full designation and by SHPDAs within five years of full designation, is unrealistic in that the level of effort that would be required to implement this one requirement in the law is staggering in view of the review process outlined in the proposed regulations. It should also be recognized that health planning and project review (Certificate of Need) are formidable tasks which have fully taxed or, in many cases, overtaxed existing agency resources at both the areawide and state level. Implementing Health Systems Plans and Annual Implementation Plans (many of which fall technically far short of what the federal government envisioned) will be an even bigger challenge in the face of limited allocations for health planning. In addition, the development process suggested by the federal government for the AR Program is bound to be arduous and protracted due to the requirement that HSAs and the SHPDA agree on and adopt similar criteria and standards, procedures, categories and definitions of covered services, review schedules, data requirements, mechanisms for obtaining the data, and so on. Supplementary information contained in the proposed regulations recognizes these problems:

"Of particular concern to the Secretary is the potentially enormous work load involved in this function. While there is very little relevant experience, there is little question that the appropriateness review function could severely tax the resources of a given agency and, therefore, weaken its entire program."

The Secretary's fears may materialize unless States are allowed to implement AR for selected services only (deemed to be of high priority to the State). Requiring the review of all services within a specified time period will dilute the effort which can be given to reviews of individual health services.

Secondly, because of the desired outcome of AR (specific findings regarding the appropriateness of an institution's provision of services), enormous pressure can be expected to be exerted on both the SHPDA and HSAs throughout the development and implementation of the AR Program. In view of this, I feel very uneasy about the notably weak legal basis with which these reviews would be performed. Foremost among my concerns are the lack of authority under which the HSAs and SHPDA can require data to be submitted by institutions, the lack of incentives for institutions to relay accurate data, and the probability that many of the institutions found "inappropriate" will bring suit against the State and HSAs on the basis that their reputations and, therefore, their abilities to perform, have been damaged unjustly. It is my opinion that any State should be very hesitant to exercise a police power (AR) that has no sanction and no State legislative authority. Our Certificate of Need Program requires the application of extensive legal resources to remain viable, as will our Decertification

Memorandum  
 March 19, 1979  
 Page Three

Program. To add the legal burdens of a third program at this time would not be in the interest of maintaining effective Certificate of Need and Decertification Programs in Wisconsin.

Thirdly, an AR Program, as proposed by the federal government, would duplicate the existing Decertification Program in Wisconsin for specialized hospital services (open heart surgery, cardiac catheterization, renal dialysis, kidney transplantation, radiation therapy, computed tomography, and neonatal intensive care). This is clearly undesirable for, as federal law is stated, we must coordinate the two programs with the realization that they overlap, are based on similar principles, and seek to achieve similar goals. We in Wisconsin are proud of our policies in this area, and are dismayed by the prospects of duplicative programs. Perhaps the statutes may be rewritten to give States with decertification authority an exemption from having to operate a duplicative program.

Finally, AR does not need to be implemented as a distinct and autonomous program to be performed by HSAs and SHPDAs. The Southeastern Wisconsin Health Systems Agency is already conducting what could be called AR as an adjunct to its existing, ongoing process of plan development. That is, its plans for institutional health services already identify to some extent the "appropriate" system of care and the actions specific institutional providers should take to implement that system.

In summary, given the limited financial resources for the support of health planning, the difficulties which would have to be overcome in developing and implementing this program, the predictable political sensitivity of the program, and the likely duplication of AR with our existing decertification program; it is reasonable to fear that an AR Program in Wisconsin and other states would fall far short of expectations at the areawide, state, and federal level. Consequently, I am urging you actively to support the following recommendations:

1. Primarily, I would like to recommend that P.L. 93-641 and the proposed regulations be amended to the extent that sanctions would be attached to appropriateness reviews, perhaps similar to the withholding of federal funds as found in the 1122 Program. Further, give States much more flexibility in the scope of services covered (by not requiring review of all institutional health services), in the manner in which the SHPDA and the HSAs define their respective roles in the development and implementation of the AR Program, and by allowing States with Decertification Programs to wholly or partially forego aspects of AR.
2. Failing this, I recommend that AR, as a distinct activity, be stricken from revisions to P.L. 93-641. In its place, legislation should be enacted requiring States to administer a Decertification Program. Minimum requirements for a Decertification Program, similar in type to those specified in Certificate of Need regulations, would buttress the legitimacy of our Decertification Program, and more directly reflect Congress' original intent with AR.

RD:jc

II. S. 230, "The Nurse Training Act"

AMERICAN NURSES' ASSOCIATION

Testimony on

S.230

NURSE TRAINING ACT

March 16, 1979

by

Joyce C. Clifford, R.N., M.S.N.

Assistant Director, and

Director of Nursing Services

Beth Israel Hospital, Boston

To

Subcommittee on Health and Scientific Research

Committee on Human Resources

U.S. Senate

Mr. Chairman,

I am Joyce Clifford, speaking on behalf of the American Nurses' Association, urging prompt enactment of S.230, the Nurse Training Act, to extend the program of assistance to nursing schools and students through fiscal 1980. As Director of Nursing Services at Boston's Beth Israel Hospital, I am also speaking as a concerned nurse administrator and a troubled employer of registered professional nurses.

My experience in nursing spans nearly 23 years in the practice of nursing in Connecticut, New Hampshire, Alabama, Indiana, and Massachusetts. For more than half of this time, I have been involved in nursing administration. Typically, the most over-riding issue that I have had to face is the proper staffing of health care programs to meet the requirements of patients and their families at a time when they most critically need assistance. Throughout my lifetime in nursing, there has been and continues to be a shortage of well prepared nurses to meet these requirements. President Carter's conclusion that "the outlook is good for adequate, sustained growth in the supply of nurses" runs contrary to the conclusions arrived at by those of us involved in the recruitment for and staffing of health care facilities. Nursing service administrators throughout this country report high vacancy rates in R.N. positions. A recent survey of the American Hospital Association revealed that of 43 state hospital associations contacted, 33 reported an overall shortage of nurses, 5 others reported a shortage of nurses prepared in specialized areas, and only 5 state associations reported no shortage of nurses. In California, 17% of the budgeted R.N. positions in hospitals are unfilled. In Milwaukee 12%, in western Tennessee 33%, in Texas 14% and in Arizona 21%. A very recent report from the Illinois

Hospital Association reports a shortage of 3,500 nurses. At the same time, a study recently completed by the Western Interstate Commission for Higher Education, a study commissioned by the Department of Health, Education and Welfare, projects an increase of at least 48% in order to meet the nation's needs for nurses in 1982. The Bureau of Labor statistics also indicate an expanding demand for nurses with projections of 240,000 more jobs in nursing by 1985. Data, however, provided through the National League for Nursing shows that even with current funding, there is a zero growth rate in basic nursing education admissions and graduations.

I am troubled by these facts. There is a shortage of nurses in this country and discontinuation of funds for the preparation of nurses will go right to the bedside of the consumer. Their health care needs will be placed at risk as the resources decline for training to meet those needs. We are all too aware of the dissatisfaction expressed by the consumer of fragmented health care. We have heard the cry for continuity and improved planning for high quality care. We have begun to make changes in the delivery system but without support for the continued preparation of well qualified nurses, we will not be able to continue.

But it is more than numbers. It is more than the high vacancy rates in registered nurse positions throughout this country. Continuation of these funds is critical for specialized areas and the development of leadership positions. The intensity and complexity of patient care show no sign of slowing down. Such complexity has a direct impact on the utilization of nurses, the need for not just more -- but for more skillfully prepared professionals as well. As you know, the average length of a patient's

hospital stay continues to be shortened. At the same time, the complexity of care required by the shortened time frame has increased substantially. The level of complexity I speak of did not exist in the past. Patients died before they reached these complex stages. We boast of the most advanced technology and most sophisticated medical regimens. When confronted with serious illness, all of us demand and expect to receive the desired outcomes of this level of knowledge. Survival alone is no longer good enough; the quality of life is of ultimate importance.

Hospitals and other health care agencies have responded to the challenge of technological complexity intermingled with the requirement to be more personal and humane in our approach to the patient. One of the most significant of these developments is Primary Nursing, where the registered nurse assumes full 24 hour accountability for the nursing plan of care for her specific patients. Primary Nursing means that the registered nurse is providing care directly to a caseload of patients rather than care through others. It means that coordination of diagnosis, therapy and education with patients, family members, physicians and other health care personnel is the responsibility of the registered professional nurse. Such coordination is crucial in today's complex system, and it demands highly trained, well prepared professionals who respond to more than the increased technology and medical specialization. It demands professionals who are prepared to confront complex ethical decisions, the serious issues of informed consent, patient's rights, and the patient's ability to cope following discharge.

Today we are faced with an increase in our aged population, a group still seriously neglected. It is the professional nurse who must assume leadership in meeting the health needs of this group. Aged persons at an

acute care hospital present multiple diagnoses and needs for care. What may be taken for granted in the younger person cannot be assumed for the elderly. Their level of dependency coupled with that complexity requires increased nursing hours and more importantly, sophisticated professionals who provide more than custodial care or studied neglect! The needs go beyond the hospital, for sophisticated, multi-service discharge planning is required; the need to extend nursing services into community-based and home health services is critical to the delivery of accessible, effective and cost-prudent health programs in the future.

A major objective of the Nurse Training Act was to prepare nurses at the graduate level to fill leadership positions in nursing service administration and supervision. While numbers of nurses is of significance to us, it is in this area, the need for well qualified nurse leaders and managers, that you will find the deepest consensus and concern among nursing service administrators. Even in Boston, with its relatively high ratio of nurses, we face serious hurdles as we attempt to fill leadership positions. At the Beth Israel Hospital, for example, an open head nurse position, our most critical first line manager, averages four to six months to fill with the right person. Even then, we find ourselves providing extensive on-the-job training and continuing education in order to prepare the nurse manager for that role. The average yearly budget responsibility of a Head Nurse at the Beth Israel Hospital ranges from \$300,000 to over \$500,000. Our Head Nurses assume complete managerial accountability for all staff assigned to their unit, staff they have interviewed and selected themselves. Such Head Nurses directly influence the efficiency and effectiveness of the delivery system. They manage an average of 30 staff members - a major responsibility in any organization.

Equally as critical is the dearth of qualified nursing service administrators in this country. It is common for executive recruiters to frequently contact practicing nursing service administrators looking for candidates to fill one of the many open positions either at the top level of administration or the second level. Results provided by 5,326 hospitals of a 1977 survey conducted by the American Society of Nursing Service Administrators shows that only 27.3% of the nurse administrators in these hospitals held a master's degree. Nearly half, or 48.1% of the nursing service administrators do not hold even a baccalaureate degree! Yet, nursing service administrators in this country assume accountability for 40 - 60% of the hospital's budget and for one-third to one-half of its personnel. We cannot afford to have unprepared people with such responsibilities. Continued support for the preparation of nurse managers and nurse administrators is thus appropriate not only for adequate numbers of nurses, not only for adequate preparation of such nurses, but also to help make the product, patient care, both effective and prudent in cost.

We appreciate the way this committee has responded to this Bill and urge prompt enactment of the Nurse Training Act, S.230, in order that the nursing resources of the future will not be further jeopardized.



NATIONAL LEAGUE FOR NURSING

STATEMENT PREPARED FOR

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
ON HUMAN RESOURCES  
U.S. SENATE

16 MARCH 1979

This statement is submitted for the record on behalf of the National League for Nursing, a coalition of nurses, allied health professionals, consumers, and health agencies--17,000 individual members and 1,900 agencies--dedicated to developing and improving the standards of quality nursing education, nursing services, and health care delivery in the United States. Among its functions, the League acts as the national accrediting agency for all nursing education programs, for which it is recognized by the Council on Postsecondary Accreditation (COPA) and the U.S. Office of Education.

Federal funding in nursing has been generous and has resulted, not only in an increase of the total number of nurses in the United States, but also in improving the quality of nursing care by allowing the expansion of creative and innovative educational programs. Nevertheless, many critical problems remain. It is necessary to look beyond the aggregate data on nurse supply, which demonstrate a surplus in the number of nurses, because these figures mask the glaring shortages and maldistribution problems that exist on geographic and local levels.

To begin with, 25-30 percent of the nurses in this country are inactive. Many reasons have been cited, such as non-competitive salaries, long and burdensome working hours, which are often caused by understaffing and an overabundance of paperwork.

That a shortage of nurses exists is likely to be obvious in a visit to any one of the great majority of hospitals in the nation--especially if one chooses to visit on a weekend. While hospital administrators and directors of nursing may vary in their description of the nurse shortage--from severe or acute to moderate--most would agree that the shortage is chronic. Examples are abundant.

At Mercy Hospital in San Diego, California, Nursing Director Frances Petersen states that the Special Care Unit has to be closed periodically

because there are not enough qualified nurses to staff it. Consequently, some patients have had to stay in Intensive Care for a greater length of time than necessary--a very costly repercussion. Also in California, the medical director of the Burn Unit at Torrance Memorial Hospital, claims that there is a very definite and chronic shortage of nurses in all of Southern California, one of the most affluent parts of the state. He emphasizes that there is an acute shortage of operating room and critical care nurses. Finally, Health Care Week (January 8, 1979) reported 500 vacant nursing positions in hospitals in Los Angeles County, which shortage has resulted in reducing the number of hospital beds, sending patients to non-county institutions, and hiring part-time nurses from nurse registries.

Southern states suffer the severest shortages. Coastal Georgia papers cite "a critical shortage of registered nurses" in the area (Statesboro, GA Herald, January 31, 1979; Savannah (GA) Morning News, January 31, 1979). An Albany, Georgia, paper (Herald, February 8, 1979) claims that local nursing shortages reflect a statewide problem which is becoming quite serious, with 3,000 vacancies in hospitals all over the state.

North Carolina papers (the Greenville Reflector of January 20, 1979; the Charlotte News of January 20, 1979) recount serious nursing shortages in spite of nearby schools of nursing. These reports recount that Greenville hospitals have been forced to turn patients away because of nurse shortages and that expensive recruitment programs conducted in Canada have failed to relieve the problem.

Even areas of the nation that have the highest ratio of nurses per 100,000 population, such as Washington, D.C., and New York City, constantly battle a chronic shortage of nurses. Florence Deutch, of Washington's Capitol

Hill Hospital, reports numerous budgeted vacancies. The American Health Care Association of New York, a trade association representing some 2,000 long-term health care facilities in the state, reports that the nursing shortage is critical in the facilities they represent.

According to 1978 statistics from the American Hospital Association, hospitals in western Tennessee reported that 33 percent of their budgeted RN positions were unfilled; in Arizona, 21 percent; in California, 17 percent; in Texas, 14 percent; and in the Greater Milwaukee area, 12 percent.

Several state studies have also been conducted indicating nursing shortages. For example, a recent study done for the Nebraska State Legislature has been used by the State Health Planning Agency to recommend an expansion of nursing education facilities in the state.

The withdrawal of Federal funds for nursing in the face of shortages such as these portends drastic consequences for the health of the nation. Within the context of anticipated societal changes--such as an increase in the numbers of elderly citizens, who already constitute 11 percent of the American population and often require extensive nursing care--this situation can only get worse.

In nursing education there is currently a zero growth-rate in the numbers of nursing schools, applicants, student admissions, and graduations, according to National League for Nursing research statistics. Thus, with no growth in the capacity to produce new nurses, there is surely no hope of solving the problems these shortages present.

Educating nurses is also a formidable problem. At present only 61 percent of full-time nursing faculty have a master's degree or higher (NLN statistics). In addition, over 800 budgeted faculty positions are currently vacant (Congressional Budget Office Report).

Continued Federal support is especially important for minorities in nursing education. Dr. Anna B. Coles, Dean of the Howard University School of Nursing, has expressed grave concern over the 75 percent of her students receiving Federal aid. "Without assistance they can't come to school, even though our tuition is very low. As it is, they go from semester to semester, not knowing whether they can return." Studies have shown (May 1978 CBO Report; 1979 HEW study by Dr. Eleanor Feldbaum) that minority nurses contribute more than others to providing better access to nursing care for disadvantaged populations. Dr. Feldbaum's work also show that employed minority nurses with graduate degrees tend to work in these areas for the greatest length of time. Minority nurses are also more likely to work in public health and community health agencies that tend to have low-income and minority clients. With the assistance of Federal funds between 1972 and 1978, the number of newly licensed minority registered nurses had doubled, from 3 percent to 6 percent (NLN research statistics.)

The Carter Administration wisely emphasizes the need for innovative health delivery systems in the nation as well as the tremendous need for primary-care providers. Nursing represents a break from disease-centered treatment. Nurses are health educators who focus on care rather than cure.

Many health experts have noted that, with all its scientific advancement, the established medical care system has seen the limits of its effective powers (Fuchs, Who Shall Live, 1977; Ehrenrich, The Cultural Crisis of Modern Medicine, 1978). Answers must now be sought in non-medical spheres, which provide a humane and cost-effective alternative. Nursing offers this possibility to the future of health care delivery in this country.

AMERICAN ASSOCIATION OF COLLEGES OF NURSING

Testimony on

S.230

NURSE TRAINING ACT

March 16, 1979

by

Linda K. Amos, R.N., Ed.D.

Dean, Boston University School of Nursing

To

Subcommittee on Health and Scientific Research

Committee on Human Resources

U. S. Senate

On behalf of the American Association of Colleges of Nursing I urge prompt enactment of S.230, the Nurse Training Act, to provide a continued program of support for nursing. We urge full support and quick passage of S.230 in order to assure stability in the planning and management of critically needed nursing programs throughout the country. The future health of our country is dependent in large part on the continued federal support of nursing programs. Nursing represents the largest aggregate and most consistent providers of health services. Nurses are providing primary health care to many sectors of our society and have been responsive to the changing demands in the health care arena. It is important to assure that a sufficient number of nurses with adequate preparation will be available to serve the nation's health care needs over the next several years. Enactment of the Nurse Training Act, as proposed in S.230, will provide support to necessary programs while a major study to be conducted by the National Academy of Sciences would be conducted to determine the need to continue specific programs of federal support for nursing. Results of this study along with other studies and data on major health problems and delivery systems will provide the basis for the formulation of a revised proposal for federal support in nursing for the future.

The urgent need for continued support of all programs contained in S.230 with a priority emphasis on graduate training in nursing, is clearly evident from the data recently obtained in a study conducted by the American Association of Colleges of Nursing on the needs and resources of schools of nursing. Forty-eight percent (48%) of the schools surveyed indicated that curtailment or loss of federal funding would necessitate elimination of a program. Approximately three quarters or seventy-three percent (73%) of the schools indicated that a loss of federal support would necessitate a significant lowering of enrollment in one or more of the baccalaureate or higher degree programs. Creation of

such a situation would be highly counterproductive in our attempts to provide more equitable access to a higher quality of health care. In order to assure adequate numbers of qualified professional nurses, many more graduates are required from baccalaureate and graduate programs.

It is clearly evident at this time that we have acute shortages of nurses prepared to function for beginning, primary, and specialized roles in every geographic area of this country. In a recent study conducted by the Western Interstate Commission for Higher Education, and supported by the Division of Nursing, Bureau of Health Manpower, entitled - Analysis and Planning for Improved Distribution of Nursing Personnel and Services, the final report of the panel of experts project a continued shortage of nurses for many years to come. The report states, "With consideration of population growth between 1976 and 1982 of 6 percent, and within the context of the current and prospective health care scene, the panel projected a need for 1,219,300 to 1,677,000 full-time equivalent (FTE) registered nurses necessary to meet the nation's needs in 1982. This projection is an increase of 48 to 104 percent above 1976 levels". These projections are based on state and national planning models which take into consideration the increasing complexity of health care, the substantial change in the scope of nursing practice, and the federally defined health goals as contained in the Health Planning and Resources Development Act of 1974. "The Panel's recommendations in relation to educational preparation of registered nurses call for an increase above 1976 levels of 308 to 458 percent prepared at the baccalaureate level and 568 to 945 percent prepared at the graduate level. ...These projections are the Panel's appraisal of what is required to provide the quality of nursing services needed to provide care acceptable and accessible to nearly all the nation, with consideration of cost containment."



-3-

At the present time, approximately 20% of the total registered nurse population has earned a baccalaureate or higher degree in nursing. With the Panel's projections of a required 64 to 66 percent of registered nurses to be prepared at the baccalaureate or higher degree level, we clearly can not approximate our needs without continued support and increased support for baccalaureate and graduate preparation in nursing.

Baccalaureate graduates are prepared as primary health care providers and provide emphasis on prevention, health teaching, education for self care and maintenance of good health in acute or ambulatory settings. They are the beginning practitioners in primary, secondary and tertiary health systems and as such should constitute the bulk of practicing nurses for the future if both care goals are to be achieved. Graduates of master's programs are prepared as advanced practitioners in primary care, clinical specialists, managers of nursing care, nurse educators, and researchers.

Data from the American Association of Colleges of Nursing study indicate that institutional support for baccalaureate programs in the form of capitation is needed to support the salaries for faculty positions, faculty development, instructional media material and some of the operational expense of the school. In selecting program options as a basis for eligibility for capitation programs, twenty-five percent (25%) of the schools indicated that they were conducting programs for recruitment of students from disadvantaged backgrounds; twenty-seven percent (27%) were providing a significant portion of clinical experiences in geographically remote areas; and forty-four percent (44%) were providing continuing education programs for nurses based on assessment of local and regional needs. Such important programs can only be continued with capitation funds and these programs are responsive to the pressing and critical health problems of our times.

-4-

In order to assure a steady supply of qualified nurses, student support in the form of scholarships, loans and traineeships are required. Data from the American Association of Colleges of Nursing study indicate that an additional 1,980 master and 165 doctoral students could pursue full time versus part-time study, if additional student support were available. An adequate base of student financial assistance would allow us to respond more quickly to the critical need for nurses prepared at the graduate level. Rising tuition levels in both the public and private sectors has resulted in a reduced number of students being supported by traineeships.

The Advanced Nurse Training funds are the only source of basic support to graduate programs. The need for more nurses with advanced preparation to work as practitioners, clinical specialists, educators, administrators and researchers is critical. It is not expected that the need can be met for many years to come if current funding levels are maintained. The American Association of Colleges of Nursing study indicates that during the 1977-1978 academic year there were 381 budgeted, unfilled faculty positions requiring minimal preparation at the master's level, and another 513 budgeted, unfilled positions for faculty prepared at the doctoral level. Projection of additional needs for the year 1980 triples for master's prepared nurses and more than doubles for doctorally prepared nurses in educational settings alone. It is estimated that the need for nurses with advanced degrees in service settings is just as critical.

Special projects support has been of tremendous assistance to schools of nursing by fostering creativity and innovation in education, including basic, advanced and continuing education. Support for special projects is necessary in order to continue the emphasis on newer approaches in nursing education which help establish community demonstration projects, inter -

-5-

disciplinary programs, and promote more effective utilization of resources.

In summary the American Association of Colleges of Nursing urges your support of S.230 as it does continue a sound program enabling schools of nursing to prepare the kinds of practitioners needed to meet national health needs. Through this program, the profession's capacity to respond to health care demands, especially the demand for primary care can be increased; and, it will assist in assuring a supply of nurses for health care delivery with advanced scholarly training for practice, teaching and research. Without stable Federal programs and adequate levels of appropriations to implement these programs, we will witness a shortage of qualified manpower to provide the health services required for the present and future and see inefficiency in the management of nursing education programs.

The President's veto of the Nurse Training Act last November was a shock to nursing consumers and other health professions. It was followed by an even greater shock when the President's request for recessions totaling \$84. million came after we had been assured that there would be no abrupt termination of nursing programs. Documented evidence fully justifies the need for federal support to nursing and the quick enactment of S.230 will assist in providing stable, effective and quality programs in nursing which meet the manpower needs of our health care system.

LKA:fp  
March 12, 1979

STATEMENT

on

EXTENSION OF NURSE TRAINING ACT

FOR THE

SENATE LABOR & HUMAN RESOURCES COMMITTEE

SUBCOMMITTEE ON HEALTH

By The

National Student Nurses' Association, Inc.

10 Columbus Circle

New York, New York 10019

NSNA Representative:

Connie Brotemarkle,  
President, Student Nurses'  
Association of Virginia

Mr. Chairman and Members of the Committee:

The National Student Nurses' Association is pleased to have the opportunity to submit this testimony to the Senate Labor and Human Resources Committee, Sub-Committee on Health.

This statement is presented on behalf of the National Student Nurses' Association, an organization with a membership of approximately 33,000 undergraduate nursing students from across the country. Our association is composed of students in associate degree, diploma and baccalaureate schools of nursing.

We strongly support an extension of the Nurse Training Act. This legislation provides vital assistance that enables many undergraduate nursing students to complete their education who otherwise would be unable to. In addition, many graduates of associate degree and diploma nursing programs are returning to school to receive the bachelor of science degree in nursing and go on for graduate education. This group of students represents a potentially large group of nurses who could be prepared for advanced and specialized nursing practice and practitioner roles. However, they must first complete their undergraduate education, an expensive and time consuming process.

Three areas in the Nurse Training Act are of specific concern to NSNA and to nursing students. These are nurse

-2-

training loans, nurse training scholarships and loan repayment. We strongly urge their continued inclusion in an extension of the Nurse Training Act.

Undergraduate nursing education has continually increased in quality and sophistication over the years, which has made it a more expensive endeavor for both schools and students. Tuition in private and public schools alike has risen sharply. In addition to tuition costs, books and supplies, nursing students face an added financial burden for uniforms and transportation to and from clinical experiences.

Nursing students have less opportunities to earn the needed funds since they often have less time to work. Clinical experiences often average 20 hours a week, in addition to classroom instruction and study time. The National Student Nurses' Association did a survey of our memberships' financial aid needs in 1978. The survey returns indicated that sixty-five percent of the respondents worked to meet the cost of their education. Fifty-one percent of the respondents indicated that they received federal financial assistance for their nursing education. Eighty-one percent of these students stated that they could not have attended school without this assistance. Fifty-one percent came from families with incomes below \$15,000 per year.

### Nurse Training Scholarships

The Nurse Training Act of 1975 provided for scholarships to be awarded to those of "exceptional financial need who need such financial assistance to pursue a course of study at the school for such year." Presently, there are 564 undergraduate nursing schools participating in the scholarship program.

Scholarships are of particular importance to nursing students from disadvantaged and low-income backgrounds. Many times federal scholarship monies are the only thing which make it possible for these students to complete their nursing education. Nursing has been successful in attracting members of minority groups into the profession, and the availability of Nurse Training scholarships has been most helpful in this.

### Nurse Training Loans

The Nurse Training Act of 1975 authorized a program of low-cost loans for full and part-time students. Presently, 448 undergraduate schools of nursing participate in the nursing student loan program.

The nursing student loan program has been quite successful and has given many students the chance to complete their nursing education. The default rate for paying back nursing student loans has been quite low. A 1973 study of 20 percent of the nursing schools involved in the nursing student loan

program, conducted by the Office of Student Assistance, showed that only approximately 2 percent of the principal loaned was in default, a much lower rate than other health professions. Liberal cancellation provisions for employment as a professional nurse have probably assisted in keeping the default rate low.

Loans have become a major source of financial aid for many undergraduate nursing students. Many have begun or continued their education with the understanding that loan money will be available. NSNA strongly believes that the nursing student loan program is necessary and should be continued. As it is, many students must seek other financial aid sources in addition to Nurse Training loans to cover the cost of their nursing education.

#### Loan Repayment

Many areas of the United States suffer from severe shortages of health care providers. Incentives for newly graduated health professionals to practice in underserved areas are badly needed to help remedy this situation. One such incentive is the Loan Repayment Program which provides for repayment funds for educational loans for nurse training costs for:

1. Up to 85 percent of all outstanding loans plus interest to graduates who enter into an agreement with



-5-

the Secretary to practice as a nurse for at least two years in a shortage area; and

2. all or part of any loans to exceptionally needy, low-income students who fail to complete their studies and cannot reasonably be expected to resume nursing studies within two years.

Nursing students, however, have not been able to utilize the loan repayment program to its fullest extent. Although the program was begun in its present form with the Nurse Training Act of 1971, information on the designated shortage areas for nursing, a necessary component of the program, was not available until an interim listing of nursing shortage areas was released in 1973. The final listing was not released until June 1976.

We believe that lack of information about this program has had a serious impact on the number of students able to take advantage of it. In the National Student Nurses' Association's survey, 65 percent of the students receiving federal aid indicated they would be willing to serve in an underserved area as an option to repay a federal loan. However, many students are not even aware that the loan repayment provision exists or how to go about utilizing it.

The loan repayment program could be an effective way to increase the number of qualified health professionals practicing in shortage areas. We urge its continuation.

The importance of nursing in the American health care delivery system has long been recognized by Congress. With its increasing educational sophistication and expanding scope of practice, nursing can help to offer many solutions to the health care delivery problems in the United States.

We urge you to approve an extension of the Nursing Training Act. We would like to thank the committee for giving us this opportunity to share our concerns with you.

TESTIMONY OF

THE AMERICAN ASSOCIATION OF  
NURSE ANESTHETISTS

Before The

SENATE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

Re:

THE NURSE TRAINING ACT OF 1979

March 20, 1979

The American Association of Nurse Anesthetists ("AANA") is a professional organization whose membership is comprised of Certified Registered Nurse Anesthetists ("CRNAs"). There are presently 15,000 active practicing CRNAs in the United States. Each one of these individuals holds unique qualifications which allow them to administer anesthesia. AANA submits that in the absence of an anesthesiologist, or a physician anesthetist with a significant background in anesthesia, that the CRNA possesses the necessary knowledge, skill and educational background to be involved in the assessment, management and administration of a patient's anesthesia requirements under the medical direction of a responsible physician. For individuals to represent themselves to the public as CRNAs, they must hold a current license as a registered professional nurse, have graduated from an accredited program of nurse anesthesia, have passed a rigid qualifying examination, and must be involved in a program of continuing education in anesthesia.

We would like to take this opportunity to indicate our strong desire that the Nurse Training Act authority be extended and at authorization levels sufficient for program growth. We were generally very distressed that last year's legislation was vetoed and we would hope that a bill quite similar to last year's bill would be passed by Congress. We are generally supportive of the American Nurses Association ("ANA") in its efforts and positions on this legislation. We worked to restore funds cut in recent proposed rescissions and we want to commend members of this Subcommittee for their efforts to this end.

- 2 -

We are also particularly interested in the passage of a bill which includes the traineeship program for nurse anesthetists. Various bills introduced by members of the House Subcommittee include such a provision and we thank those members sponsoring or co-sponsoring such bills. / We are distressed that S. 230 contains no such provision and hope that the Senate will eventually pass a bill with such a provision in it.

We would now like to address ourselves to the provisions relating to nurse anesthetist training.

1. The Educational Program and Training of a Nurse Anesthetist

As this testimony will point out, the CRNA is a much needed element within the health care system. To understand the type of educational program the CRNA must complete (and the type of program for which we are requesting Federal support), allow me to delineate the current educational requirements for CRNAs. Building on the professional nursing base, the student nurse anesthetist must complete the following program:

Orientation to Anesthesia Practice - 45 contact hours; Chemistry and Physics of Anesthesia - 45 contact hours; Advanced Anatomy, Physiology and Pathophysiology - 120 contact hours; Principles of Anesthetic Management - 60 contact hours; Pharmacology of Anesthetic, Adjunctive and Ancillary Drugs - 60 contact hours; and Clinical Correlative Conferences - 35 contact hours. Also included in the clinical program is a requirement of a minimum of 600 hours of actual anesthesia time in which clinical instruction is provided in situations where students actually administer the anesthesia. Other requirements include a minimum

of 450 cases of anesthesia actually administered with these cases distributed according to types of techniques required and variety of drugs used. With this type of background, there should be no doubt as to the ability of the CRNA to provide the patient with quality anesthesia care.

Training programs are graduate-level programs for registered nurses. Training involves 18 to 24 consecutive months of course work and clinical instruction and a certificate of graduation is received when the program is successfully completed. All training programs are accredited by an accreditation body approved by the Office of Education. There are presently 165 of such programs while there were 225.

## 2. The Dimensions of Nurse Anesthetist Practice

As previously stated, the CRNA is a vital element within the health care system in the United States. Nationwide, nurse anesthetists are providing safe, reliable and economic anesthesia care to approximately one-half of all of the patients undergoing anesthesia. Included in this statistic is the fact that in rural areas nurse anesthetists account for approximately two-thirds of all anesthesia care rendered. Throughout many areas in the country, nurse anesthetists are the only providers of anesthesia care. (In a 1971 survey of hospitals, forty percent of all of the hospitals surveyed had only nurse anesthetists on the staff.) According to figures published in the February, 1978 issue of Anesthesiology, the national mean population ratio for active practicing nurse anesthetists is 7.20 per 100,000. This figure compares with a distribution of 4.64 anesthesiologists per 100,000. A break-

down of these figures on a regional basis will show that the areas with the thinnest distribution of anesthesiologists have the highest distribution patterns for nurse anesthetists.

### 3. Supply and Need for Nurse Anesthetists

Not only are CRNAs a vital segment of the health care system within the United States, there is a definite projected need for more nurse anesthetists in the future. According to a 1976 study by the H.E.W. Bureau of Health Manpower on "Supply, Need and Distribution of Anesthesiologists and Nurse Anesthetists in the United States, 1972 and 1980" (HRA:77-31), there is a projected need of from 22,000 to 25,000 nurse anesthetists for 1980. Obviously, there is a serious shortage in this field which provides approximately half of all anesthesia services in the United States. Inclusion of the traineeships for students in schools of nurse anesthesia in the Nurse Training Amendments of 1979 will be the first step on the part of the Federal Government to rectify this shortage.

The fact that nurse anesthetists are a significant group in the delivering of anesthesia services was pointed out by Dr. Feldstein of the University of Michigan in a study of the 16,500,000 surgical procedures performed in 1974. The largest percentage of anesthetics administered, 48.5%, was rendered by CRNAs; 38.3% was rendered by anesthesiologists, including both board-certified and non-board-certified; 9.7% by physicians other than anesthesiologists; and 3.5% by registered nurses other than CRNAs. A further breakdown of those procedures indicates that certified registered anesthetists administered approximately two-thirds of all the anesthesia procedures in

hospitals smaller than 100 beds. Anesthesiologists tend to congregate in larger hospitals, over 200 beds, where they administered 47.5% of all anesthesia compared to 42.5% for Certified Registered Nurse Anesthetists.

#### 4. Economics of Nurse Anesthetist Services

The majority of nurse anesthetists are salaried hospital staff, whose services are billed by the hospital as part of hospital operating room costs. According to the U.S. Department of Labor, Bureau of Labor Statistics, "Industry Wage Survey of Hospitals, August, 1975 - January, 1976", the average hourly wage for nurse anesthetists working in 21 major metropolitan areas was \$8.02. Based on a 40-hour work week, the average annual earnings for a nurse anesthetist would be \$16,681.60. This figure compares with full-time equivalency earnings of hospital-based anesthesiologists of \$80,000 as determined by a Health Care Financing Administration "Study of the Reimbursement and Practice Arrangements of Provider-Based Physicians, December, 1977" (Contract No. 600-76-0055). An analysis of these two salary figures indicates that where nurse anesthetists are providing anesthesia services, the cost to the patient should be substantially lower than where anesthesiologists are providing the services. Even where a team approach is used, the fact that some of the time utilized is of CRNAs rather than anesthesiologists would indicate efficiency and cost savings.

#### 5. Need for Federal Training Support

Nurse anesthetists are clearly a shortage field in health care. Possibly twice as many nurse anesthetists are needed



for 1980 as are practicing now according to the HEW study cited above.

One of the obstacles to obtaining them is the lack of financial support for trainees. Training programs are generally for two years; a substantial graduate program. A survey of all educational entities providing these programs indicates that the average monthly stipend from the school is only \$259 or about \$3,000 per year. (Stipends for research careers are, for example, \$10,000 to \$13,000.) The total of tuition and all costs is, at a minimum, \$5,000 to \$6,000 per year to the student; presenting a deficit of \$2,000 to \$3,000. Students are generally unable to hold part-time jobs because the nurse anesthesia program runs for 18 to 24 consecutive months. In addition, rotating clinical schedules prevent part-time work in the evenings and on weekends. The financial problems mentioned above deter students from entering this field. Loans are difficult to obtain and entry level salaries are in the \$15,000 range with average salaries after 5 years at \$20,000. Such salary levels are not conducive to borrowing particularly if an individual has a family to support.

Traineeship support authorized at \$2 million and \$3 million in the first two years would assist in meeting the average \$2,000 a year or more financial deficit of students. About 1500 students a year could benefit at the rate of about an additional \$150 a month stipend from such a program. \$150 a month was the average deficit in 1977 of these students relative to their living needs.

To the institution, the major financial burden is in

- 7 -

making stipends available to students. With living costs what they are and no time for part-time work, stipends are critical. Institutions put up \$3,000 on the average toward these living and educational costs of \$5,000 to \$6,000. Limited resources prevent institutions from offering more aid or from offering aid to more students. Federal support to the institutions for traineeships will allow a greater number of students to enter programs since some programs are prevented from expending due to the lack of stipend money. It will also relieve the burden on low income students to permit their entry into the program. In addition, with the Federal Government picking up some of the traineeship costs, institutions will be able to devote some of their future funding to program expansion.

It should be noted that the number of nurse anesthetist training programs has decreased by about 60. These were the smaller programs. Federal support may prevent such harmful attrition and stimulate the development of new programs.

With respect to operating costs of nurse anesthetist training programs, patient care hospital revenues support such activity as staff, supplies and teaching space. We note with satisfaction, that such costs of hospitals are excluded from the recent hospital cost containment legislation offered by Senators Talmadge and Dole.

We appreciate the opportunity to testify and your Subcommittee's attention to this matter.



# AMERICAN MEDICAL ASSOCIATION

535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610 • PHONE (312) 751-6000 • TWX 910-221-0300

JAMES H. SAMMONS, M.D.  
Executive Vice President  
(751-6200)

March 21, 1979

The Honorable Edward M. Kennedy  
Chairman  
Subcommittee on Health and Scientific Research  
Committee on Labor and Human Resources  
United States Senate  
Washington, D.C. 20510

Dear Senator Kennedy:

The American Medical Association submits the following comments on S. 230, the Nurse Training Amendments of 1979. This bill would extend funding for the program of federal assistance for nursing education through September 30, 1980.

The AMA recognizes the important role of nurses in the delivery of health services. An adequate supply of properly trained nursing personnel is essential to maintaining the continuity and effectiveness of patient care. We believe that the federal government has played an important role in the support of nursing training and we recommend that support be continued.

The primary need now is to insure adequate financial support for students and to continue assistance to existing facilities so they can maintain their educational programs. In view of the current budgetary restraints, such an approach is particularly desirable.

Therefore, we support an extension of the authorization of appropriations for the following nurse training programs: capitation grants to schools of nursing, special project grants and contracts, advanced nurse training programs, traineeships for advanced training of professional nurses, student loans, and scholarship grants.

We request that this letter be made part of the Subcommittee's official hearing record on S. 230.

Sincerely,

A handwritten signature in dark ink, reading "James H. Sammons".

James H. Sammons, M.D.

JHS:RF/sr



## AMERICAN MEDICAL ASSOCIATION

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JAMES H. SAMMONS, M.D.  
Executive Vice President  
(751-6200)

April 20, 1979

The Honorable Edward M. Kennedy  
Chairman  
Subcommittee on Health and Scientific Research  
Committee on Labor and Human Resources  
United States Senate  
Washington, D.C. 20510

Dear Senator Kennedy:

It is our understanding that the Committee on Labor and Human Resources has ordered S 230, to extend federal support for nurse training, reported to the full Senate for its consideration. We have previously expressed support for major portions of this legislation in a letter to the Subcommittee.

We also urge the Senate, when it considers S 230 on the floor, to support its provisions to increase the amount of funds that could be made available to medical schools under the financial distress grant program. Several medical schools face severe financial crises unless interim federal assistance can be made available in sufficient amounts. The unique contributions of these schools are widely recognized. Financial distress grants can be an important step toward resolution of their economic difficulties.

In accordance with these views, we urge the Senate to act favorably on this legislation to continue support for nurse training and to expand the availability of financial distress grants to medical schools.

Sincerely,

*James H. Sammons, M.D.*  
James H. Sammons, M.D.

JHS:RF/dap



## VIRGINIA NURSES' ASSOCIATION

1311 HIGH POINT AVENUE • RICHMOND, VIRGINIA 23230 • 804-353-7311

### STATEMENT TO U.S. SENATE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

Friday, March 16, 1979

The members of the Virginia Nurses' Association are grateful to the Senate Appropriations Committee for recommending lesser cuts in funding for the Nurse Training Act than those requested by the Administration, \$15.75 million compared with \$84.097 million.

We would like to state, however, that nursing does, in fact, need the total appropriations of \$122 million as provided by the Continuing Resolution for Fiscal Year 1979. As the health care field expands and becomes more demanding, the need will continue for professional nurses prepared above the basic educational level. President Carter may be correct in his statement that there is an adequate number of nurses in this country to meet the nation's health needs. The real shortage occurs in the quality of preparation for the increasingly sophisticated care being delivered by professional nurses. The classified advertisements in our daily newspapers bear witness to the fact that there is a great demand for well educated nurses who are competent in performing today's complicated procedures.

The Honorable David E. Satterfield, III, Virginia member of the House of Representatives, has called for a study in his proposed bill, House Bill 1820, to explore future needs for professional nurses and other sources of support for nursing education. Certainly we agree with his proposal and will assist in the effort to find such sources.

We realize, of course, that the Congress must look for ways to reduce spending in the future, but we agree with the Honorable John J. Cavanaugh, when speaking to the amendment by Congressman Harley Staggers in the House of Representatives on March 6, 1979, that we have a right to expect we can rely upon the previous commitments and extensions of funding and to complete our plans for nursing education based upon those commitments.

It is regrettable that our profession did not have available at the hearing of the House Subcommittee on Health and Environment, any representatives to speak to the proposed rescissions and their effect upon nursing programs. For this reason, we requested permission to speak to the Senate Subcommittee on Health and Scientific Research today.

Thank you very much.



## American Psychiatric Association

1700 Eighteenth Street, N.W., Washington, D.C. 20009 • Telephone: (202) 797-4900

March 13, 1979

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The Honorable  
Edward M. Kennedy  
Chairman  
Subcommittee on Health and Scientific Research  
310 B Senate Courts Annex  
Washington, D. C. 20510

Dear Mr. Chairman:

On behalf of the American Psychiatric Association, a medical specialty society representing over 24,000 psychiatrists nationwide, I wish to express our continued strong support for Section 202 of the "Nurse Training Amendments of 1979" (S.230). We believe it is critical to expand the availability of National Health Service Corps (NHSC) scholarships to individuals whose residency training extends beyond the three year deferral period presently authorized and appreciate and commend such amendment.

To buttress, support and provide further rationale for the intent of Section 202 to provide the Secretary of Health, Education, and Welfare the flexibility to extend the three year residency deferral, we would appreciate your favorable consideration of an amendment, hereinafter set forth, which would designate psychiatry as a medical shortage specialty.

As you know one of the President's Commission on Mental Health major recommendations was:

"The Health Professions Educational Assistance Act be amended to designate psychiatry as a medical shortage specialty and require medical schools to set aside a certain proportion of their residency positions for this discipline."

Section 202 alleviates existing law's clear disincentive to medical students with an interest in psychiatry since as the Subcommittee knows psychiatric residencies require four or five years of training. Also, presently a student interested in psychiatry either cannot take advantage of the program in the first instance, or alternatively enters the program and fulfills the payback provision inadequately and incompletely trained especially in the subspecialties of child and geriatric psychiatry.

-2-

Such restrictions upon the utilization of the NHSC by prospective psychiatric residents are particularly damaging in view of the serious shortage in manpower confronting psychiatry as a discipline.

As the President's Commission on Mental Health pointed out, the shortage of psychiatrists is attributable to several factors, to wit:

"In recent years, there has been a reduction in the numbers of American medical graduates entering psychiatric residency training. A severe restriction has also been placed on the entrance into the country of foreign medical graduates, many of whom enter psychiatric residency training and practice in State hospitals. Over half the psychiatrists and other physicians staffing these facilities are graduates of foreign medical schools."

We understand that the 50 percent figure cited above ranges as high as 90 percent in some states. Moreover, the proportion and number of American medical graduates entering psychiatry training dropped from 12 percent in 1970 to 6 percent in 1976, and in that latter year, 39 percent of all residencies in psychiatry were filled by foreign medical graduates (FMGs).

With the loss of the FMGs as the result of PL 94-484, coupled with the declining numbers of medical school graduates entering the field of psychiatry, the discipline is now suffering and will continue to suffer a severe shortage. Recent National Institute of Mental Health (NIMH) figures indicate there is a need for over 2,500 psychiatrists in State and county facilities alone; that two-thirds of all counties in the United States have no psychiatrists. Moreover, there is evidence from NIMH and HEW that psychiatrists are in short supply not only in critical State and county facilities, but by 1981 there will be an overall shortfall of psychiatrists of at least 10,000.

Such appeared to be the Senate's legislative intent as it considered the legislation which became PL 94-484, Senate Report 94-887 stated: "The Secretary is required to seek to assure that calculated in a national aggregate for each year, there is an appropriate percentage of residencies in psychiatry." Also, the Conference Report stated "nothing is to be construed as prohibiting the development of appropriate numbers of such residencies to meet national needs."

Moreover, if Congress approves the Administration contemplated Community Mental Health Systems Act, which would stimulate initiatives to provide services to the 20-32 million Americans identified by the President's Commission on Mental Health as in need of mental health care, including those in what currently are psychiatric manpower shortage areas, the need for adequately trained psychiatrists will further expand.

Accordingly, we recommend that Section 202 of S.230 be amended as follows:

On page 8, between lines 11 and 12 insert the following:

(b) Section 2(a)(4) of the Health Professions Educational Assistance Act of 1976 (relating to Findings and Declarations of Policy) is amended by inserting before "physician" the following: "except for psychiatry which is a medical shortage specialty".

We understand that the Health Resources Administration has already suggested reserving 10-15 percent of its medical student scholarships in the NHSC program for those interested in specializing in psychiatry. Yet no efforts to date have been made to designate psychiatry a medical specialty shortage. The proposed amendment would be an important Congressional commitment to that goal and the need for amending the NHSC scholarship deferral eligibility.




-4-

We believe the amendment we propose, in combination with the bill's broadening of the service corps deferment for payback, will provide the foundation for a renewed and revitalized and adequately trained psychiatric manpower pool. It will not only help diminish the manpower shortage in underserved geographic areas of the country, but will provide the leadership and direction to any new mental health system established by Congress in the future.

We hope you will make this communication part of the hearing record and look forward to working with you.

Respectfully,

  
Jules H. Masserman, M.D.  
President

JHM:JBC:TF:mag

Joseph A. George, CRNA  
 Chairman, Government Relations Committee  
 S. Dakota Association of Nurse Anesthetists  
 4701 Steamboat Circle  
 Rapid City, South Dakota 57701

March 27, 1979

The Honorable Senator Larry Pressler  
 United States Senate  
 Washington, D. C. 20515

Dear Mr. Pressler:

I would appreciate the opportunity of providing you with some thoughts, on S-230, for the official committee transcripts.

First and most important is specific mention of allocations for financial support of traineeships for registered nurses to be nurse anesthetists. This is imperative in any legislation earmarked for nurse training. The importance being:

1. Students are seldom eligible for existing state or federal programs because of restrictive residency rules or previously earned salaries as a registered nurse.
2. Students find it very difficult to supplement their income with outside work because of rotating clinical schedules and the fact that the schools of nurse anesthesia extend for twenty four consecutive months.
3. Finally, previously earned stipends for anesthesia students are being curtailed as part of cost containment for the associated hospitals.

As I have mentioned in one of our earlier correspondence, nurse anesthetists provide the majority of anesthesia across the nation, including two-thirds of anesthesia in rural areas. Nurse anesthetists, CRNA's, play a vital role in the delivery of anesthesia services in the State of South Dakota. As you may know, there are two schools of nurse anesthesia in South Dakota. Mount Marty College in Yankton and McKennan Hospital in Sioux Falls both offer anesthesia programs. You might also be interested in knowing that Mount Marty was the first program in the nation to offer a baccalaureate degree in nurse anesthesia.

As a member of the health care field and one concerned about the increasing cost of health care, I feel that an investment in nurse anesthesia training is a step toward health care cost containment.

Sincerely,

*Joseph A. George, CRNA*

Joseph A. George  
 Chairman, Government Relations Committee

## III. S. 590, "The Clinical Laboratory Improvement Act of 1979"

STATEMENT OF THE  
AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS  
ON  
S. 590, CLINICAL LABORATORY IMPROVEMENT ACT OF 1979  
PRESENTED TO THE  
SUBCOMMITTEE ON HEALTH AND SCIENCE  
COMMITTEE ON LABOR AND HUMAN RESOURCES  
UNITED STATES SENATE

March 21, 1979

The American Society of Clinical Pathologists is a non-profit, educational and scientific medical specialty society representing nearly 23,000 pathologists and other medical laboratory professionals. Our members practice in a wide variety of laboratory environments: hospitals, universities, independent laboratories, military and veterans' hospitals, and federal, state and local government facilities. Our organization is vitally concerned with the quality of health care in this nation, and we are committed to upholding the very highest standards in the clinical laboratory.

Because of the ASCP's fifty-seven year commitment to the improvement of the delivery of clinical laboratory services, we have a great interest in the proposed Clinical Laboratory Improvement Act. We believe that laboratory services throughout the United States are the finest in the world. They are constantly being improved through the dedication and hard work of individuals and professional organizations in the field.

-2-

Much attention has been given in the press, in Congress, and in the medical profession to the quality of laboratory services, and to fraudulent activity in clinical laboratories. While this type of activity is offensive to everyone, it is particularly so to those of us in the profession. Thus, we want to do everything possible to ensure that all laboratories are of high quality and conduct their business with honesty and integrity. We commend the Committee for its interest and concern in this area.

We would like to emphasize, however, that the vast majority of our profession are honest, hard-working and dedicated professionals. Further, many controls, both private and governmental, exist to monitor the quality of clinical laboratories. Rules and regulations authorized by the Clinical Laboratory Improvement Act of 1967 are presently in effect. All hospital laboratories have extensive quality review systems of personnel and procedures. Many states have laboratory licensure laws or laboratory certification programs, and legislation is pending in several additional states to require such programs.

In a time of cost-consciousness, when government spending and bureaucratic inefficiency are the subject of widespread criticism, it does not seem prudent to enact legislation which will in many ways be duplicative of present efforts. S.590 would mandate costly regulation of the laboratory which would not necessarily improve the quality of laboratory services. Because we do not see

a clearly-established need for the regulation provided for in S.590; we must state our general opposition to the Bill.

We recognize the desire of the Committee to assure the best in health care for the citizens of this nation, and we share that desire. It is in this context that we offer our comments and recommendations regarding S.590.

In Section 7 of the Bill, titled "Hospital-Associated Physicians," it is proposed that the Social Security Act be amended in such a way that the term "physicians' services" is re-defined. Under this provision, pathology services would be physicians' services only when a physician personally performs an act or makes a decision with respect to a patient's diagnosis or treatment. In order to qualify as a physician's service, a service must be personally performed or personally directed by a physician, and must be of such nature that its performance by a physician is appropriate.

This provision is not a measure of "clinical laboratory improvement" but is a major reordering of the nature of medical practice. It will have dramatic impact on the entire practice of medicine. Further, the proposed amendment to the Social Security Act will only diminish the quality of pathology services now being provided as an integral part of medical practice and patient care, and has the potential to cause difficulties in obtaining quality laboratory services in small hospitals throughout the country. We

recommend that this entire section be deleted from S.590, and we support the existing definition as stated in Section 1861(q) of the Social Security Act: "The term 'physicians' services' means professional services performed by physicians, including surgery, consultation, and home, office and institutional calls."

Because certification of laboratory personnel is one of the major activities of our Society, the area of personnel standards is one of great concern to us. We have offered testimony on these provisions in previous versions of the Clinical Laboratory Improvement Act. As we have in previous testimony, we support the "Studies Respecting Requirements for Laboratories and Laboratory Personnel," provided for in Section 379 of S.590. The studies called for in this section would result in a body of valuable data on laboratory personnel, and the relationships of certification, proficiency examinations and training requirements to overall laboratory performance. As one of the major organizations involved in the certification of laboratory professionals, the ASCP would welcome such a study.

We do not, however, support the prescription of personnel standards for all technical personnel in the laboratory, as provided for in Section 372 (b) (4), until such time as a study demonstrates that such prescription by the Secretary is necessary. Personnel needs vary in each laboratory, and with well-established, highly-respected, private sector certification available, setting high standards for laboratory professionals, laboratory directors and

supervisory personnel can staff their laboratories according to their individual needs and be assured of a high-quality staff. It is our belief that the private sector of the health care field has a responsibility to ensure competence of personnel, and the ASCP and its Board of Registry are carrying out that responsibility.

If the study mandated by S.590 should demonstrate a need for further personnel standards to be established, the appropriate legislative action can be taken at that time. The ASCP would be pleased to assist in the development of recommendations, should the need be established by this study.

Let there be no question whatsoever that we wholeheartedly support the concept of qualified personnel in the laboratory at all levels. We do believe, however, that if personnel standards are enacted, in this bill or any future legislation, they should not prescribe requirements for laboratory personnel below the level of laboratory director and supervisors. It is our understanding that the Secretary of HEW is presently reviewing personnel standards developed by HEW Staff under existing authority, which prescribe requirements only for directors and supervisors. Since we have not had the opportunity to review these proposals, we cannot comment on them. We would, however, concur with the testimony presented to this committee on March 16, 1979, by Assistant Secretary for Health Doctor Julius Richmond, in which he pointed out that personnel standards are being developed, alleviating the necessity to include these

provisions in S.590.

Because of the critical responsibilities of a laboratory director, and of the other professionals in supervisory positions, it is crucial that they be highly qualified. We would like to recommend, in fact, that the position of laboratory director carry the requirement of an M. D. degree. These highly-qualified practitioners of medicine should then be given the freedom to make decisions regarding the necessary training and experience for bench-level technologists and technicians. These decisions can be made on the basis of the workload of the laboratory, the availability of personnel in the area, and other variables. We suggest that if the personnel standards provisions must be included in S.590, they be revised to retain the language of the Clinical Laboratory Improvement Act of 1967, in which the Secretary was empowered to establish standards for " . . . qualifications of the director of the laboratory and other supervisory professional personnel necessary for adequate and effective professional supervision of the operation of the laboratory . . ."

We have noted that an employee protection clause, which has appeared in previous versions of this legislation, is also included in S.590, in Section 375,(d), and that this portion of the bill has been expanded and now outlines the procedures for filing complaints and for collecting damages. We certainly agree that no laboratory employee should feel threatened as to his job security,



should he be aware of and wish to report violations of laboratory standards. However, employees' rights are protected in existing laws, presently administered by the Fair Employment Practices Commission and the Equal Employment Opportunity Commission. To include these provisions in S.590 is unnecessarily duplicative.

Finally, we would like to comment on Section 373 of S.590, titled "Agreements." We support this section of the bill, and are pleased to see the bill providing for cooperation between the government and the private sector. There are fine programs in existence, being conducted by private, nonprofit organizations to inspect laboratories, administer proficiency testing, and examine laboratory personnel. The College of American Pathologists conducts a laboratory inspection and accreditation program and an interlaboratory proficiency testing program. These CAP programs have recently been deemed to meet laboratory inspection requirements of the Joint Commission on Accreditation of Hospitals and, thereby, the standards for Medicare-approved laboratories. Our own ASCP Board of Registry is another example of a private program, this time in the examination of clinical laboratory personnel. The Board of Registry has been certifying laboratory professionals since 1928, certifies in three generalist and ten specialist categories, and has examined more than 183,000 individuals in its fifty-one year history. We strongly support the provisions in this legislation which would permit the Secretary to take full advantage of the expertise that has been developed in the private sector.

We would also like to suggest that in part (b) of this section of S.590, a sentence be inserted that would allow state and local agencies as well to enter into such agreements with private, nonprofit organizations.

We would like to conclude our statement by re-emphasizing our commitment to the very highest standards in the clinical laboratory. The American Society of Clinical Pathologists is pleased to have this opportunity to comment on S.590.


**AMERICAN HOSPITAL ASSOCIATION**

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**STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION**  
**BEFORE THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH**  
**OF THE**  
**SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES**  
**ON**  
**S.590, THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979**

March 21, 1979

The American Hospital Association represents over 6,400 health care institutions (including most of the nation's hospitals, extended and long-term care institutions, mental health facilities, and hospital schools of nursing) and over 27,000 personal members. We are pleased to present our views on S.590, the Clinical Laboratory Improvement Act of 1979.

**IDENTIFICATION OF THE NEED FOR CLINICAL LABORATORY REGULATION**

The AHA has consistently supported programs designed to assure safe and competent health care in hospitals and other health care institutions, including programs that contribute to prompt availability of reliable clinical laboratory services. One example of this long-standing commitment has been AHA's relationship with the Joint Commission on Accreditation of Hospitals (JCAH), which the Association founded in conjunction with other leading professional health organizations. The JCAH is a voluntary, independent commission that defines standards for health care delivery in the institutional setting, including standards related to laboratory services.

While we strongly support the concept of assuring the reliability of hospital tests, we question the efficacy of establishing yet another federal regulatory program as a vehicle to achieve this goal. We believe any legislation affecting the operations of these laboratories should result in demonstrable improvement in the quality of

their operations at a minimum increase in costs. Carefully designed studies, providing complete and valid evidence of the costs and benefits of additional regulation, should serve as the basis for a program such as that proposed by this legislation.

We recognize the fact that S.590 specifically acknowledges the need to evaluate the impact and cost-effectiveness of standards applied to clinical laboratories and we endorse its proposal that studies be undertaken in this regard.

The bill calls for studies designed to:

- assess the adequacy of existing certification standards and state licensing laws;
- assess the need for certification of employed personnel to assure their continued competency in laboratory testing procedures;
- determine the number of persons in the technical laboratory personnel labor pool who would qualify for employment under such standards as those proposed by this legislation;
- analyze the effects of the costs and quality of laboratory tests and procedures by requiring that a lab may not be licensed unless its staff meets the standards;
- analyze the ~~ramifications~~ ramifications of such personnel standards for rural clinical laboratories, which will encounter difficulties in recruiting and retaining qualified personnel; and
- analyze and evaluate the present performance of laboratories located in physicians' offices, and the advisability of continuing the present policy of exempting such labs from the personnel and testing standards.

However, it is inappropriate that these important effects be evaluated only after the bill's new standards are enacted. We feel that there are distinct advantages, from an economic and administrative viewpoint, in conducting the studies first and then acting in consonance with the findings. Undertaking evaluative studies at a

time when the field is adjusting to the implementation of new standards will undermine the reliability and validity of the information gathered. For example, the proposed standards for personnel will involve significant modifications in the staffing patterns of some hospitals. Further, the specification of mandatory proficiency testing for all clinical labs presents many technical problems, due to the present state-of-the-art, which we will address later in this statement.

The Association further recommends that this legislation direct the Secretary of HEW to take advantage of developed expertise in the private sector in undertaking the several studies called for in the bill. Appointment of an advisory panel comprised of individuals representing appropriate professional groups—a provision of earlier versions of this legislation—would assure the participation and cooperation of those directly affected and most knowledgeable in the construction and interpretation of these evaluative studies. We would recommend an advisory committee on clinical laboratories to be established on enactment of this bill, including representation from hospital administration.

#### FRAUD AND ABUSE

One of the purposes for clinical laboratory legislation was the problem of more effectively dealing with fraud and abuse, and with standardizing the quality of services in clinical laboratories. P.L.95-142, the Medicare/Medicaid Anti-Fraud and Abuse Act, includes a number of fraud and abuse provisions under Medicare and Medicaid.

Further, in 1978 HEW promulgated quality control and proficiency testing regulations applicable to hospital-based and independent laboratories. Because of these developments, we believe that this legislation should be carefully evaluated against provisions already in place in law and regulation. We are concerned that this

proposal could needlessly add to the plethora of regulations that already apply to hospitals and laboratories.

#### PERSONNEL STANDARDS

The AHA is concerned about the detailed personnel standards prescribed in Section 372(b)(4). While we agree that all laboratories should meet minimum personnel standards for directors and supervisors, we believe that specific requirements for laboratory personnel below the supervisory level would be costly and unnecessary in achieving the goals of this legislation. Many capable, experienced individuals without formal credentials are now performing the tasks required in providing satisfactory laboratory services, and we believe it is desirable and necessary that those who are performing be allowed to continue to provide services, particularly in small and rural hospitals.

Development of rigid and uniform personnel standards for non-supervisory employees, moreover, could retard desirable and cost-effective innovations in manpower utilization. Evolution of new technology and improved techniques for performing tasks impacts significantly on the skills and knowledge of the personnel required to perform laboratory tests. For example, in the past, certain procedures have required the skill and knowledge of a highly trained laboratory worker to accomplish an individual test. Today, advancing technology, prepackaging and automation of some tests have, in many cases, eliminated the need for advanced skills in completing such tests.

#### PROFICIENCY TESTING OF CLINICAL LABORATORIES

S.590 specifically calls for two types of testing procedures for evaluating the performance of clinical laboratories.

General Proficiency Testing

Section 372(d) requires that the Secretary develop job related proficiency and practical examinations, design mechanisms to assure the continued competency of personnel, and administer annual on-site testing of employees of clinical laboratories.

Many hospitals have been participating in effective and worthwhile proficiency testing programs on a voluntary basis because of the desire of directors of hospital clinical laboratories, medical staffs, and hospital managers to improve the quality and reliability of clinical laboratory services. The College of American Pathologists (CAP) conducts an extensive inspection and accreditation program. Over 5,000 hospital laboratories participated in the college's various proficiency testing programs last year and more than 1,300 of the laboratories were actually inspected by the CAP teams. The proficiency testing programs of the American Association of Bioanalysts include a total of 800 hospital-based laboratories. AHA has encouraged hospital participation in these high quality, evaluative programs, and we believe such efforts have had a beneficial impact on the quality of laboratory services.

These voluntary arrangements have also demonstrated that tailoring the proficiency testing program to the needs of specific institutions, and to the scope of services actually provided, is essential to a fair and meaningful testing program. For many small hospital laboratories, requiring proficiency in tests which are not representative of the actual daily workload could result in performance that failed to meet prescribed standards. Thus, such laboratories would be in jeopardy of losing their licenses, which in turn could lead to the termination of all hospital services. In our view, proficiency testing aimed at improving the quality of the clinical laboratory performance should be designed to measure performance on tests actually conducted on a routine basis.

We strongly believe that any national standards must be flexible enough to take into account the variation in type and scope of laboratory services needed and provided in the range of communities in the United States.

#### Blind Proficiency Testing

A recent Center for Disease Control (CDC) study, Comparison of Performance with Mail-Distributed and Blind Proficiency Testing Samples, by Louis C. LaMotte, Jr., Sc.D, et al., noted the difficulty of arranging for blind proficiency testing on a routine basis. This difficulty relates to the methodological problems of transporting human specimens under controlled conditions and camouflaging the submission of blind samples to laboratories, as well as to the significant costs involved in such a program. We believe that no such requirement should be implemented unless its application proves cost effective. Our reservations are based on the following:

- efforts to use proficiency testing have been on a limited sampling or model program basis;
- neither CDC nor any professional group has developed procedures that can be used nationally to assess laboratories, reliably on a blind test basis;
- mechanisms do not exist for assuring that blind samples submitted by a testing service remain unidentified, and were such mechanisms to be developed, they would be difficult, if not impossible, to implement; and
- the cost of establishing and using blind testing universally has been estimated as prohibitive by organizations that have attempted such testing.

We recommend that blind proficiency testing should not be incorporated as a requirement for clinical laboratories unless a methodology is developed through research and it can be demonstrated that the application of blind proficiency testing results in improvement in the quality of services on a cost effective basis.



## APPLICATION TO SMALL, RURAL HOSPITALS

The AHA is seriously concerned about the rigid application of national standards to small, rural hospitals. While S.590 provides for a two-year delay in implementation of such standards--specifically, standards prescribing qualifications for laboratory personnel in certain clinical laboratories in rural areas--the bill does not include authority for the Secretary of HEW to grant waivers once the period has ended.

We believe that such authority is essential, to deal with the problems of rural hospitals which experience temporary shortages of qualified laboratory personnel.

Rural hospitals encounter great difficulty in recruiting and retaining qualified health personnel for their laboratories. For one reason, there is insufficient challenge in routine types of testing. For another, there are limited options for professional development and advancement. For still another, there are restricted social opportunities, particularly for technicians trained in urban areas. Finally, there are disadvantageous geographic factors, such as isolation and harsh climate.

Because of the difficulty which rural hospitals have in recruitment and retention of qualified personnel and the unlikely probability of significantly modifying the social, professional, and residential environment in which rural hospitals are located, the AHA recommends that a renewable waiver of personnel requirements be provided for hospitals located in isolated areas where there is a shortage of qualified laboratory personnel. Consideration for granting this waiver would take into account the volume and type of tests that are essential to the provision of services in an otherwise medically underserved area and the geographic location of the hospital.

The waiver would be granted to rural hospitals where (1) such waiver would not create a health hazard for the community served by the institution, and (2) where the hospital demonstrates that although it is making a good-faith effort to comply with the federal

personnel standards, it has either been unable to attract the necessary number of qualified personnel or, because of the loss of a qualified laboratory worker, has found itself out of compliance with the federal requirements.

Such a waiver was endorsed last year by the 100-member Congressional Rural Caucus, when similar legislation was considered by Congress.

We envision that utilization of this waiver might follow much the same pattern that has developed with the waiver from the Medicare 24-hour nursing requirement. This waiver provision, enacted by Congress as an amendment to the Social Security Act in 1971 (P.L.91-690), has been important in assuring access to needed hospital care for Medicare beneficiaries. It permits the Secretary of HEW to waive the requirement for Medicare-participating hospitals to have 24-hour registered nurse staffing, provided the hospital was making a good-faith effort to achieve compliance with the requirement and provided no undue health hazards existed. Although initially there were some 600 hospitals granted waivers under this provision, recent HEW data indicate that 36 hospitals are presently waived. This suggests hospitals' efforts to achieve full compliance, notwithstanding the potential of a renewable waiver.

The AHA recommends that Section 372 (f) (2) of S.590 be amended to read:

"(2) During the two-year period and, upon approval by the Secretary,  
for subsequent two-year periods, beginning on the date that national standards for clinical laboratories first take effect under section 372 the provisions of such standards prescribing qualifications for laboratory personnel shall not apply to a clinical laboratory which--

"(A) the Secretary determines is located in a rural area (as defined by the Secretary) in which individuals with the qualifications prescribed by such provisions are not available,

"(B) performs services solely for hospitals and licensed physicians, dentists, or podiatrists (or any combination of such practitioners) located within such rural area, and

"(C) provides the Secretary satisfactory assurances that it will take such actions as may be necessary to train individuals to meet such qualifications on a continuing basis or to employ individuals with such qualifications."

Moreover, because of the hardships facing rural hospitals with fewer than 50 beds and because the medical staff of these institutions frequently consists of five doctors or less, the AHA recommends that such hospitals be granted the same consideration extended to physicians', dentists', and podiatrists' offices and to rural health clinics which provide clinical laboratory services.

The AHA recommends that Section 372 (f) (3) (A) (i) be amended to read:

"(i) which is located in the office of, and operated by, a licensed physician, dentist, or podiatrist, or a group of not more than five such practitioners, or in a rural hospital of less than 50 beds, or in a rural health clinic, as defined in section 1861 (aa) (22) of the Social Security Act, and"

Acceptance of these amendments would permit the Secretary to recognize and deal constructively with the special problems encountered in rural and often isolated areas.

#### OTHER ADMINISTRATIVE CONCERNS

##### On-Site Unannounced Inspections

We are concerned that the authority for unannounced, on-site inspections is too broad. Such authority at the discretion of the Secretary could result in highly disruptive inspections which would interfere with orderly and efficient hospital

functions. Moreover, if such inspections were conducted without appropriate warrants, they would neither be consonant with the spirit of the Fourth Amendment nor with pertinent Supreme Court decisions.

Research and Insurance Laboratories

We support the exemptions from the national standards for laboratories engaged in research and those which perform tests for insurance purposes. Regulation of such facilities would not further the goals and objectives of this proposed legislation.

Laboratory Standard-Setting and Inspection

We support the provisions of the bill which allow the Secretary to enter into agreements in this regard with qualified nonprofit, private entities. It is undesirable to develop fragmented regulatory mechanisms for each hospital activity, which would inevitably increase the cost of providing health services and subject hospitals to multiple inspections which could otherwise be handled through a single survey. Acceptance of voluntary inspection and accreditation programs would help avoid the need for federal or state government programs.

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The AHA appreciates the opportunity to express its views on the Clinical Laboratory Improvement Act of 1979 and we will be pleased to provide any additional information the Committee may request.

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**Joint  
Commission**

875 North Michigan Avenue Chicago, Illinois 60611  
*on Accreditation of Hospitals* (312) 642-6061

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John E. Affeldt, M.D.  
President

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March 20, 1979

The Honorable Edward M. Kennedy  
Chairman, Subcommittee on Health  
and Scientific Research  
Senate Committee on Labor and  
Human Resources  
310 B Senate Courts Annex  
120 C Street, N.E.  
Washington, D.C. 20510

Dear Mr. Chairman:

You will find enclosed with this letter a statement of the Joint Commission on Accreditation of Hospitals (JCAH) on S.590, The Clinical Laboratory Improvement Act of 1979.

We respectfully request that this statement be included in the hearing record of your subcommittee on this proposed legislation.

You will note from the enclosed statement that the JCAH has three major concerns with the present construction of S.590, namely:

- it inaugurates a universal Federal clinical laboratory licensure program while Medicare, Medicaid and Interstate laboratories could appropriately have been excluded because they are already subject to Federal control,
- the bill would seem to require qualified public and nonprofit private laboratory accreditation/certification entities to become the government's agent for laboratory certification purposes (thus destroying voluntarism in this area); and
- finally, States granted licensure determination responsibility would be allowed to inspect clinical laboratories in spite of a

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Member Organizations

American College of Physicians  
American Hospital Association

American College of Surgeons  
American Medical Association

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oint Commission on Accreditation of Hospitals

The Honorable Edward M. Kennedy

March 20, 1979

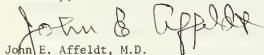
Page Two

prior Secretarial finding that such laboratories successfully participating in qualified voluntary accreditation programs meet the Federal licensure standards.

As you can see our concerns all relate to what we perceive to be disincentives for perpetuation of qualified voluntary programs of laboratory accreditation/certification. We seek your assistance to improve this legislation in this regard.

Thank you for your kind attention to this matter.

Sincerely,

A handwritten signature in dark ink, appearing to read "John E. Affeldt". The signature is fluid and cursive, with the first name "John" being more prominent.

John E. Affeldt, M.D.  
President

PEM:JEA/bc

cc: Senator Jacob Javits

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**Joint  
Commission**

 875 North Michigan Avenue Chicago, Illinois 60611  
 on Accreditation of Hospitals (312) 642-6061
 

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 John E. Affeldt, M.D.  
 President
 

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STATEMENT  
 OF THE  
 JOINT COMMISSION ON ACCREDITATION OF HOSPITALS  
 ON S590  
 THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979  
 BEFORE THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
 OF THE  
 SENATE LABOR AND HUMAN RESOURCES COMMITTEE  
 MARCH 16, 1979

Mr. Chairman, I am John E. Affeldt, M.D., President of the Joint Commission on Accreditation of Hospitals (JCAH). I am pleased to have this opportunity to present the views and recommendations of the Joint Commission to the Subcommittee on Health on S.590, the Clinical Laboratory Improvement Act of 1979.

JCAH/Historical Background

Before addressing myself to this legislation, I would like to present background information about JCAH. In 1951 the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association (which withdrew in 1959 to participate in its own national hospital accreditation program) joined with the American College of Surgeons to form the Joint Commission on Accreditation of Hospitals. The JCAH was incorporated in Illinois as a not-for-profit corporation.

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 Member Organizations

 American College of Physicians  
 American Hospital Association

 American College of Surgeons  
 American Medical Association
 

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As stated in Article I of its Bylaws, the purposes of JCAH are:

- (1) to establish standards for the operation of hospitals and other health-related facilities and services;
- (2) to conduct survey and accreditation programs that will encourage members of the health professions, hospitals, and other health-related facilities and services voluntarily to
  - (A) promote high quality of care in all aspects in order to give patients the optimum benefits that medical science has to offer,
  - (B) apply certain basic principles of physical plant safety and maintenance, and of organization and administration of function for efficient care of the patient,
  - (C) maintain the essential services in the facilities through coordinated effort of the organized staffs and the governing bodies of the facilities;
- (3) to recognize compliance with standards by issuance of certificates of accreditation;
- (4) to conduct programs of education and research and publish the results thereof, which will further the other purposes of the corporation, and to accept grants, gifts, bequests, and devises in support of the purposes of the corporation; and



- (5) to assume such other responsibilities and to conduct such other activities as are compatible with the operation of such standard-setting, survey and accreditation programs.

This voluntary approach to quality assurance is unique to the United States and Canada. Other countries have approached quality assurance through government regulation, whereas, in this country health providers took the initiative to use the voluntary approach, which has resulted in an effective system of coordination between the public and private sectors.

#### Role of JCAH

In addition to its Hospital Accreditation Program, the JCAH also establishes standards and offers voluntary accreditation programs throughout the United States for adult psychiatric facilities, children's and adolescents' psychiatric facilities, drug abuse treatment and rehabilitation programs, alcoholism treatment and rehabilitation programs, community mental health services, long term care facilities, services for mentally retarded and other developmentally disabled persons, and ambulatory health care organizations. Collectively the accreditation programs of the Joint Commission survey over 4,500 facilities, services and programs in the course of a year, and approximately 7,300 facilities, services and programs currently hold JCAH accreditation. Represented in this statistic are over 70% of the hospitals in the United States.

It should be recognized that JCAH, rather than directly involving itself in the evaluation of patient care and services, fixes the responsibility for performance of these functions with the hospital and its organized medical staff. The accreditation process of JCAH is a significant mechanism through which providers of

health care and related human services have been effectively motivated through voluntary professional efforts to provide higher levels of quality and service.

#### Hospital Accreditation Program Standards

The JCAH standards for hospital accreditation as contained in the Accreditation Manual for Hospitals, 1979 edition, have a long history of development. The first "Minimum Standard for Hospitals" was issued by the American College of Surgeons (ACS) in 1917. During the following 35 years ACS conducted a Hospital Standardization Program which caused a natural evolution in hospital standards. In 1952 when the JCAH survey program was implemented these minimum standards of the ACS program were utilized.

The adopted minimum standards were revised six times by the JCAH Board of Commissioners between 1953 and 1965. Then in August 1966, the Board of Commissioners voted "to review, re-evaluate, and rewrite the hospital accreditation standards and their supplemental interpretations to raise and strengthen the standards from a level of minimum essential to the level of optimal achievable and to assure their suitability to the modern state of the art."

Consequently, the standards underwent extensive revision, resulting in the 1970 edition, called, for the first time, the Accreditation Manual for Hospitals (AMH). Since then, the Manual has undergone continuous review and revision to keep abreast of the state of the art.

Please note that all references to sections of S.590 which follow refer to the proposed sectional amendments to the Public Health Service Act.

Clinical Laboratory Licensure - Cost Consequences

Mr. Chairman, the JCAH fully supports the purposes of S.590. We are not, however, persuaded that Federal licensure of clinical laboratories is the most economical method of improving clinical laboratory standards. We believe the objectives of this bill are on their way to achievement by the Department of Health, Education and Welfare under the existing authority of Sec. 1861(s)(11) of the Social Security Act and Sec. 5(a) of the Clinical Laboratory Improvement Act of 1967. In other words the Department currently has authority to set the standards that would be imposed by this legislation and is doing so.

Recommendations:

That your subcommittee consider whether the additional federal costs associated with administration of a federal licensure program for clinical laboratories will yield a benefit which clearly exceeds similar benefits achievable under existing legislation, and

That the calculations of this cost include:

- a Director of Clinical Laboratories, attendant staff and other support services;
- financing of the state laboratory licensing inspections mandated by Section 373(b); and
- processing applications from 50-80 thousand physicians for licensure exemption and attendant continuing DHEW

review of the results of proficiency testing in such office laboratories as is required by Sec. 372(f)(3)(C).

Lack of Clear Understanding of Problem Legislation Would Correct

House Report 95-1004, March 24, 1978 on HR1909, The Clinical Laboratory Improvement Act of 1978, indicated that Federal licensure legislation is needed because there are currently no federal controls on nearly 5,000 independent interstate laboratories not receiving reimbursement under Medicare or Medicaid or on 50-80 thousand laboratories in physician offices. While noting that some of these laboratories participated in proficiency testing programs and that some were located in states with effective state laboratory licensure programs, the report nonetheless concluded that little is known about the types and volumes of procedures performed in such laboratories. Hence, little is really known about the extent and scope of the problem this proposed legislation would remedy.

Recommendation:

That this legislation be limited to authorization for appropriate studies of clinical laboratory problems including but not necessarily limited to those studies specified in the proposed section 379. The clinical laboratory standards which would be implemented under this proposed legislation are already in the process of being mandated under existing law in the case of laboratories serving Medicare or Medicaid patients or engaging in interstate commerce hence the standard setting authority of S.590 is not a condition precedent for the needed studies.

Redundant Inspections

Mr. Chairman, this subcommittee has historically demonstrated sensitivity to the costs of government programs and in this connection has supported voluntary programs designed to assure provider qualification for participation in governmental programs.

As you know, Section 1865 of the Social Security Act provides that hospitals accredited by the JCAH are deemed to meet the requirements for participation in the medicare program except for utilization review and institutional planning. In this connection the Department is presently involved in making the necessary regulatory adjustments to extend deemed status to these latter areas as well. Section 373(a) of S.590 may also allow the Secretary to find that clinical laboratories in hospitals accredited by JCAH qualify for licensure under this Act. Although we certainly support this interpretation, we believe your subcommittee should have at least two concerns with respect to it.

The first concern is that states which must be granted primary licensure responsibility in accordance with Section 373(b) would be empowered to conduct inspections of clinical laboratories participating in voluntary accreditation programs recognized by the Secretary. Permit me to elaborate. As stated earlier, the role of the JCAH is to encourage safe and competent health care in hospitals and other health care institutions, including the timely provision of reliable clinical laboratory services. JCAH standards undergo continuous review and revision. In this connection our Board of Commissioners adopted changes in our Hospital Standards for Functional Safety and Sanitation, Social Work, Special Care Units, Respiratory Care, Dietetic Services, Home Care Services and, of particular

interest to this subcommittee, Pathology and Medical Laboratory Services, at its April 8, 1978 meeting. The Department of Health, Education and Welfare subsequently found our Pathology and Medical Laboratory Service Standards equivalent to the Medicare standards in this area that became effective last November 24. Incidentally, these new Departmental standards are equivalent to those imposed on interstate laboratories under the Clinical Laboratory Improvement Act of 1967. We are persuaded that these standards will not differ significantly from standards which would ultimately be promulgated under this proposed legislation. It appears to us that S.590 would allow the Secretary to make a finding under Sec. 1865 of the Social Security Act and Sec. 373(a) of the proposed legislation that clinical laboratories in hospitals accredited by the JCAH meet Federal standards promulgated under Sec. 372 of the Act. Nevertheless, it also appears that, subsequently, no State exercising its authority under Sec. 373(b) to determine whether laboratories meet requirements for licensure would be bound by such a finding. We believe this means that a State would be allowed to conduct its own duplicative hospital laboratory inspection program despite a Secretarial finding that a qualified public or nonprofit private entity, such as the JCAH, is making inspections and accrediting hospitals with integral clinical laboratories using standards at least equivalent to those promulgated under this legislation. It should be noted that many states currently conduct (at State expense) state laboratory licensure programs which do not recognize a laboratory's participation in a voluntary accreditation program. We would suggest that Sec. 373(b) of this proposed legislation would provide Federal financing of such State activity. Considering the number of letters we receive from hospitals concerning the costly and time-consuming nature of redundant inspections, we cannot imagine that you and your staff are not deluged with similar epistles. We believe this bill can be improved in this regard.

Recommendations:

That Section 373(b) be expanded to restrict Federal financing of State (Federal licensure) inspections of laboratories participating in voluntary programs recognized by the Secretary in accordance with Section 373(a).

The second concern, although related, is broader than the first. As you know, the JCAH accredits hospitals, not distinct parts thereof. We are concerned that hospital clinical laboratory services are being singled out for separate regulatory attention apart from all other services in a hospital. We submit that it is undesirable to develop fragmented regulatory mechanisms for each hospital service. Such activity would inevitably increase the cost of providing health services and subject hospitals to even more inspections. We believe you may be able to make a very constructive change in this legislation aimed at discouraging fragmentation and encouraging efficiency and voluntarism in this area. It is in this vein that we make the following recommendations.

Recommendations:

Retain the requirement that clinical laboratories participating in Medicare meet the standards promulgated under Section 372 but amend S.590 to provide that qualification for participation in Medicare provides automatic qualification for Federal licensure.

Agreements and Assistance

Section 373(a) of the Act could be interpreted as requiring qualified public or nonprofit private entities to enter into a contract with the Secretary to become

the government's agent for purposes of inspecting clinical laboratories. Clearly, regulations implementing this legislation could require this. The JCAH, as a matter of principle, would not undertake surveys of hospital clinical laboratories as an agent of the government because of our board's position that participation in the JCAH program must be voluntary. A review of some of the history of this legislation suggests the intent that the JCAH accreditation program could provide an avenue for laboratory licensure.

Senator Javits, in his introductory remarks on S.705 in the Congressional Record of February 10, 1977, stated that S.705 would "authorize the Secretary and enforcing State to utilize the services of private, nonprofit entities for the provision of inspection and proficiency testing services."

Page 14 of the Committee Report (HR95-1004, July 12, 1978) on HR10909 states, "The bill provides that if the Joint Commission on Accreditation of Hospitals imposes standards for hospital laboratories that are at least equivalent to the national standards, the Secretary (or the State, in the case of a State with primary enforcement responsibility) may deem a laboratory in a JCAH-accredited hospital to be in compliance with the national standards." Under present law, a clinical laboratory located in a hospital accredited by the JCAH is deemed to meet Medicare's health and safety standards. The Secretary is authorized, however, to set higher standards than those applied by JCAH and may in such case, conduct inspections to verify compliance with those standards. The bill conforms to this present Medicare policy by providing that JCAH accreditation will be acceptable as evidence of a hospital laboratory's compliance with national standards, if the Secretary determines that the JCAH's laboratory standards are at least equivalent



to the national standards."

Mr. Chairman, the language of this section of the bill must clearly be changed if you wish to perpetuate voluntary programs of clinical laboratory certification/accreditation. There is nothing voluntary about an inspection conducted by an organization acting as an agent of the government.

Recommendations:

That Section 373(a) be amended to provide that, in addition to the agreements presently provided for, the Secretary and States may make findings that clinical laboratories voluntarily participating in qualified public or nonprofit certification/accreditation programs meet Federal licensure requirements.

Mr. Chairman, we appreciate this opportunity to express our views on the Clinical Laboratory Improvement Act of 1979.

BRIEF POINTS OF CONCERN  
TO THE  
COLLEGE OF AMERICAN PATHOLOGISTS ON S. 590,  
THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979  
March 20, 1979

The College of American Pathologists supports the principles of assuring high quality laboratory procedures -- a principle that was the main purpose of previous bills proposing the enactment of a new CLIA. S. 590, however, must be opposed for it no longer has the assurance of quality as its main purpose. It proposes many measures which appropriately belong in separate legislation. Its purported sections dealing with the improvement of quality will lead only to increased regulation and increased cost of laboratory services. Strong opposition is directed at the following sections.

Hospital-Associated Physicians -- Section 7

Section 7, in its entirety, will cause a serious disruption in the delivery of medical care in this nation. The redefinition of physicians' and pathologists' services contained in section 7 is not a quality improvement measure. Section 7 is a major reordering of the nature of the practice of medicine, particularly in the field of pathology and should be deleted in its entirety. This issue is currently being addressed in a bill pending before the Senate Finance Committee, S. 505.

Inspections and Proficiency Testing: Section 3

Requirements for unannounced, supervised on-site proficiency testing should be removed from the bill. Blind proficiency should be applicable only to those cases where fraud is suspected.

Personnel Standards: Section 3

Personnel qualifications should be established for the director and supervisor levels only. Because of the critical importance of medical direction

of a clinical pathology laboratory, provisions should be included that only a physician, preferably a pathologist, should direct a clinical pathology laboratory. This bill should not deal with requirements for laboratory personnel since DHEW is finalizing personnel standards for all clinical laboratories.

Penalties for Violation of the Law or Non-Compliance with Standards:  
Section 371 (c)(2) and Section 375

S. 590 should clarify these sections so that it is clear that penalties apply only when such unlawful actions are performed knowingly and willfully. Much of the discussion of fraud and abuse in the laboratory is outdated. Any remaining cases of abuse or fraud that were identified as of possible national concern are now being addressed under HEW authority contained in P.L. 95-142, which gives wide authority to the HEW Inspector General.

Employee Protection: Section 375 (c)

The College does not believe that there exists sufficient justification for the inclusion of this provision in S. 590. Over the past several years there have been, at the most, several allegations of employer retribution. This provision is unnecessary and will do nothing to improve the quality of laboratory services offered to patients.

Statement of the College of American Pathologists  
On S.590, Clinical Laboratories Improvement Act of 1979  
Submitted to the Health Subcommittee  
Committee on Labor and Human Resources  
United States Senate  
March 21, 1979

The College of American Pathologists welcomes the opportunity to submit testimony on S.590, the Clinical Laboratory Improvement Act of 1979.

The College of American Pathologists (CAP) is a nonprofit, voluntary medical specialty organization, headquartered in Skokie, Illinois. The CAP was founded in 1947, and has nearly 8,000 physician-members who practice the medical specialty of pathology. CAP Fellows are certified by the American Board of Pathology.

Our members practice in hospitals, in independent medical laboratories, in medical schools, in military institutions, and in various facilities of federal, state and local governments. In addition, our members work in medical laboratory research institutions.

The College of American Pathologists has a proud record of involvement and leadership in advancing the quality of the performance of clinical laboratories and the results of that performance.

We would like to state at the outset that we consider the standard of work in the majority of clinical laboratories in the United States to be outstanding and unequalled by any other nation. This statement is supported by extensive published data based on the work of the vast majority of U.S. laboratories.

As you know, high quality is the mark of a professional. Thus, we are proud to note that the quality of laboratory service has advanced

progressively during the past two decades as new technology and procedures have been created. This notable advance has occurred under our present system.

Historically, the College has supported legislation aimed at providing realistic, practical and economically achievable mechanisms for assuring quality laboratory services to the public. Indeed, high quality laboratory services are in the best interest of both the American public and the profession. When we have been critical of legislation dealing with clinical laboratory improvement, our chief aim has been to call attention to legislative provisions which we believe would fall far short of their mark.

Thus we have supported the principles embodied in previous CLIA bills introduced in both the Senate and the House of Representatives.

Pathologists greatly appreciate the efforts of Senator Javits in the area of laboratory improvement. Tremendous strides have been made in the laboratory greatly improving the accuracy and efficiency of the procedures performed. It is because of these great strides since CLIA '67 was enacted that the College must seriously question the need for a CLIA in 1979.

S.590 is not the same type of bill as S.705, the Clinical Laboratory Improvement Act of 1977. S.590 purports to be a bill to improve the quality of laboratory services in this nation. It is in fact, however, an amalgam of regulatory constraints which will not improve quality--but will raise costs.

Let it be clear that the College strongly supports the principle of the highest possible quality of laboratory services. The programs of the College are designed to assure that quality. However, we cannot support a bill that promises high quality but delivers instead only increased regulation.

We are concerned over the language, especially examples cited, used by the remarks introducing S.590 to the Senate on March 8, 1979. For example, an error rate of 8-25 percent of all laboratory tests is cited. DHEW has withdrawn its use of these out of date figures.

The statement that "there is rampant fraud in clinical laboratories" is incorrect, inflammatory and a disservice to the many physicians, technologists, and technicians who serve the patient of this nation honestly and with the highest quality services.

We believe the references to a 1976 HEW survey revealing serious deficiencies in 74 percent of the laboratories inspected and CDC proficiency testing results are misleading when used out of context as they were in the opening statement.

We would now like to comment on several specific sections of the bill.

#### Hospital-Associated Physicians: Section 7

The College believes most strongly that section 7 of S.590 must be withdrawn in order to avoid a serious disruption of the delivery of not only laboratory services but also medical services provided by virtually all physicians.

The Committee should be aware that this section title "Hospital-Associated Physicians," is misleading. Subsection (a)(1) proposes to redefine physicians' services in general, not just pathology services.

We cannot believe that by any stretch of the imagination that this section will improve the quality of laboratory services--the stated purpose of S.590. It is an issue being addressed in a bill, S.505, pending before the Senate Finance Committee.

The College opposes any redefinition of physicians' services as is suggested in section 7 (a)(1) of the bill. We support the existing definition as stated in section 1861(q) of the Social Security Act: The term physicians services means "professional services performed by physicians, including surgery, consultation, and home, office and institutional calls."

We believe that it is not appropriate to address a reimbursement problem by trying to arbitrarily change the time-honored definition of physicians' services. Such change will be at the expense of all in the health care system - the patients, the providers, the insurers, and the Government.

Section 7 proposes to amend existing law by stating that a service is a physician's service except any service that a physician may perform as an educator, an executive or a researcher; or any professional patient care service unless the service (a) is personally performed by or personally directed by a physician for the benefit of the patient, and (b) is of such nature that its performance by a physician is appropriate.

Although this change appears under the heading of hospital-based physicians it must be perfectly clear that the proposed change would affect all physicians because of its location in the statute. The impact on many physicians by such a redefinition would be profound even though its implications may not yet be widely appreciated in the medical community. Physicians employing physicians' assistants, nurse practitioners, operating room and obstetrical technicians, laboratory and X-ray technologists and technicians, anesthetists, respiratory technicians,--all such physicians ultimately would be affected.

The College is of the opinion that the redefinition as it appears in subsection (a)(1) would seriously impair the administration of the Act.

Defining the term "personally performed by or personally directed" would inevitably lead to a complex maze of regulations. For example, we wonder how these regulations would define "personally directed" in an equitable fashion assuring optimal patient care. We also believe that inevitably, complex regulations would result in so much red tape as to impair the quality of physicians' services provided to patients.

The redefinition is not a cost containment measure. It is a major reordering of the nature of the practice of medicine which we believe to have a secure foundation in history. It is a "reform" that is in reality a revolution. The practice of medicine would change dramatically.

The wholeheartedly support the American Medical Association, which stated in its testimony (March 14, 1979) on S.505:

"The writers of regulations, armed with this proposed statutory language, could arbitrarily change the practice of medicine as recognized today to the detriment of both the patient and the profession."

We Strongly urge the Committee to recognize what this redefinition is - a restructuring of the practice of medicine - not a simple cost containment measure. Thus, we strongly urge the deletion of section 7 from this bill.

#### Pathology Services:

Subsection (a)(2) proposes to specifically redefine pathology services in a manner very similar to the general redefinition of physicians' services as discussed above. Our preceding comments apply quite well to this redefinition of pathology services, for it proposes to arbitrarily restructure what is and is not a physician's service in the delivery of clinical pathology services.



Separation of the services provided by pathologists to patients and other physicians is inappropriate.

We of course recognize that payment of didactic classroom teaching and basic research is not one of the objectives of the program. When we speak of patient care, we speak of providing laboratory data and clinical pathology consultation essential for the assessment, diagnosis, treatment and management of disease in the individual patient. When we speak of education, we speak of the need for the pathologist to educate the attending physician in a consultative role on patient-based matters. When we speak of research, we speak of the development or refinement of procedures for daily use to improve the care of the individual patient.

The statement that supervision and quality control are "appropriately performed by non-physician personnel" recognizes only a small part (the manual/technical portion) of the responsibilities often performed personally by technical personnel, but does not recognize that the policy and procedure setting, standardization, evaluation and action initiation must be the medical responsibility of the pathologist director of the laboratory. This is especially critical for the hospital laboratory. Because a non-physician can under certain circumstances perform designated delegated quality control and supervisory functions, this fact does not change the existence of or the nature of the physician's service in quality control and supervision and the clear patient-related services that these represent. This is in itself a cost containment program. Years ago, all services offered by a pathologist were personally performed by him. What do you think the cost would be today if this type of service were still required?

We believe that the unique services provided by pathologists as the medical director of the clinical pathology laboratory are most appropriately provided by a physician. Who would want anyone other than a physician evaluating the quality control data pertaining to a test required by you or a member of your family when release of misleading result or withholding of an accurate critical value from your physician could lead to a delay or some inappropriate treatment.

There is strong evidence to support the CAP position that there is a professional (physician's) component in every laboratory procedure. This evidence is based on not only actual daily practice, but also legislative and regulatory history.

In every-day practice, the pathologist must correlate clinical data, test results, and other data to determine a diagnosis for a patient. The requirement for this decision-making transcends the arbitrary division between personally performed or personally supervised.

Because of their medical training and experience, pathologist can see warning flags in subtle abnormalities, which take on meaning not only in a single test but in the context of multiple tests.

We believe that the definition of physician services should remain as presently stated in the Medicare law. Singling out any group of physicians for adverse treatment would be a radical change from Congress' Medicare policy.

Although there was some controversy on how to treat hospital-based physicians during the time surrounding the passage of Medicare in 1965, the legislation that finally passed placed hospital-based physicians with their clinical colleagues, under Part B, to a large extent because of

the strong sentiment in Congress against any major disruptive effect on the contractual arrangements between physicians, hospital and patients. The details on managing the Medicare program were yet to be determined by regulation, but the issue had clearly been joined in Congress and those who favored treating hospital-based physicians the same as all other doctors prevailed.

In sum then, we urge most strongly the deletion of section 7 from S.590 because of the disastrous effect it will have on the practice of medicine and because of its misplacement in this bill.

Personnel Standards for Clinical Laboratories: Section 3

With respect to the development of personnel standards, the College believes that specific requirements for the categories of personnel should not be set. We are pleased to note that the standards to be written and the qualifications which will be necessary for laboratory personnel will take into consideration appropriate training, experience and results of examinations.

As we have stated in previous testimony before this Committee, the College has adopted a position that professional educational and training standards should be applied only to the director and supervisory personnel of the laboratory. The College firmly believes that the qualifications of the laboratory director are the most crucial ones for assuring the best possible laboratory performance.

Because of the acute care situation of a hospital and the primary need for medical judgment in a hospital-based laboratory director, the College believes that the director of a clinical pathology laboratory must be a physician. The Physician director is the person who must assume

medical, legal, moral, and ethical responsibility for the analyses performed and/or diagnoses established by him or under his direction.

Further, we do not believe personnel standards should be promulgated until the implications have been fully evaluated by the study authorized in Section 379 of S.590. To do otherwise could be expensive and potentially damaging to health care in the United States.

As we said earlier, the College believes that a clinical pathology laboratory must be directed by a physician, preferably a pathologist. We take this position because we know that the performance of a laboratory procedure, especially for an acutely ill patient, involves a great deal more than just the performance of a laboratory test. It involves medical judgment and interpretative and consultative services by the physician, and the assurance that quality control procedures present in the laboratory are medically sound.

Recognition should be given to the established continuing education programs provided for laboratory directors and technical personnel which are conducted by the College and the American Society of Clinical Pathologists. Language should be included in the bill to the effect that participation in these continuing education programs meet requirements for the assurance of continued competence. We do not believe it appropriate that the director of a laboratory who participates in approved programs of continuing education be subject to any requirements for annual "tests" measuring levels of competence.

#### Proficiency Testing and On-Site Inspections: Section 3

S.590, contains provisions which require supervised unannounced on-site proficiency testing of clinical laboratories and optional blind proficiency testing of clinical laboratories.

Proficiency testing is a tool to be used by laboratories as a part of a program to maintain and improve quality of services and to make it possible to compare the performance of the laboratory against comparable laboratories across the country. The College conducts a proficiency testing program that serves both of the oabove stated functions.

The College also has an Inspection and Accreditation program in which an extensive on-site inspection of the laboratory is make. The inspection team, composed of pathologists and medical technologists, performs a physical inspection of the laboratory; reviews record keeping and quality control procedures; and observes the performance of procedures. These programs, proficiency testing, and inspection and accreditation are, as you can see, two distinct programs.

We do support on-site inspection. We have been a leader in its development and application. However, we believe on-site inspection, llke proficiency testing, is a tool to be used in assuring quality laboratory services rather than a tool to assure regulatory compliance.

Recently, the College reached an agreement with the Joint Commission for the Accreditation of Hospitals (JCAH) which provides for the acceptance of College inspected laboratories (under the Inspection and Accreditation Program) as meeting or exceeding JCAH and Medicare requirements for hospital laboratories. The College is the only medical specialty organization recognized by the Secretary as being equivalent to Medicare standards. In addition, the College I & A program is now accepted by several states as meeting state laboratory licensure requirements.

The College is strongly opposed to universal unannounced on-site proficiency testing and blind proficiency testing.

It should be clear, however, that we do support on-site inspection of laboratories and would support limited on-site testing when it would contribute materially to a decision to accredit a laboratory.

#### On-Site Proficiency Testing

The College is strongly opposed to a national system of on-site proficiency testing, particularly when unannounced. Logistically, on-site proficiency testing requires that a qualified inspector be an individual with proper scientific and technical background. If not, he/she would have no idea as to the correctness of the procedure taking place.

Much attention has been given to the stated success of the on-site proficiency testing program in New York City. However, a critical factor is often overlooked. The large number of laboratories in the city are geographically very close, thereby reducing travel time and the necessary number of inspectors. If a comparable program were implemented on a statewide basis, an unreasonably large number of qualified inspectors would be required to be on the road virtually all the time. If the on-site program is to apply to all clinical laboratories (approximately 13,500), the number of qualified inspectors needed would be multitudinous.

If the proficiency of the laboratory is to be adequately tested, then a sampling of the range of the tests performed must be tested. Some laboratory procedures may take 3-4 hours to complete--many average 1-2 hours. Some tests, especially in the areas of parasitology and bacteriology, may take 2-3 days to complete; some over a week. In addition, many laboratories may run automated tests that can be batched on only one or two days per week.

The number of qualified inspectors that would be needed, the wide geographical distances separating laboratories in many parts of the country, and the complexity and the time consuming nature of a variety of laboratory procedures present severe logistical problems that would seriously hamper, if not prevent, the application of an on-site proficiency testing program on a nation-wide basis.

The problems of cost are easily related to the above stated logistical problems. The salary expense of the great number of inspectors needed would be enormous. The situation is compounded when the cost of travel and lodging are added in those geographically dispersed areas. The fact that inspectors may spend many nonproductive hours just waiting for tests to be completed is anything but cost effective.

Other costs associated with on-site testing are the need for sophisticated proficiency testing samples that must be able to withstand the rigors of time and travel without deterioration. The number of such samples necessary makes the consideration of cost most important. If on-site testing is to be used as a tool of interlaboratory comparison, then the samples must meet national criteria that would make possible the comparing of national results.

How will assay results of the samples be kept confidential? Will the inspectors have multiples samples to choose from? How can we assure sample stability, accuracy and interpretability? Can all laboratories be treated fairly and equally? Can we prevent massive litigation arising from this process? Won't the educational value be destroyed? How will the results be used?

The consideration of costs begs the question, "who will shoulder the burden?" The answer is that this specifically unknown, but substantial

amount, will be borne by the already strained Social Security Trust Fund.

### Blind Proficiency Testing

The College would like to register strong opposition to the inclusion of a provision calling for blind proficiency testing. This position is based on the belief that a national system of blind proficiency testing is neither practical, possible nor desirable. The term itself is ambiguous and open to many substantially different interpretations. We would be happy to provide the Committee with information about the problems and consequences of attempts at blind surveying.

The question of blind proficiency testing was discussed in October of 1975 at a National Conference on Proficiency Testing held in Washington, D.C. under the sponsorship of the National Council on Health Laboratory Services (NCHLS). The NCHLS is a broadly based group which includes both federal and state agencies and private professional organizations. A number of recommendations resulted from the conference. One of those recommendations was:

"Blind and on-site proficiency testing may be useful in certain special circumstances but routine widespread application is precluded by insurmountable logistic and cost problems."

A statement by a New York City Health Department employee supports this recommendation:

Sylvia Blatt, M.S., New York City Department of Health, "In order to determine the actual quality of daily testing, it would be necessary to send blind specimens through the usual channels. However, this would be extremely expensive and would require the cooperation of medical practitioners."



We oppose both universal blind and on-site proficiency testing on similar grounds -- prohibitive cost and difficult logistics.

We would suggest that on-site and/or blind proficiency testing programs be used in those instances where there are indications that a laboratory is engaging in fraudulent practices. To require such a program of all laboratories would be immensely costly and would offer little, or no assurance that laboratory performance will be enhanced to any great extent.

#### AGREEMENTS: Section 373

The College supports the concept of this section which provides an opportunity for nonprofit entities such as the College to develop or to continue existing programs which have standards as stringent as those developed by the Secretary and/or the state.

The College has participated with both federal and state government in upgrading the quality of laboratory services through agreements granting equivalency to College programs of inspecting and accrediting interstate laboratories. This agreement was formulated under the provisions of the Clinical Laboratory Improvement Act of 1967. We wish to continue in our role of providing expanding services which are equivalent to regulatory requirements under law. However, the wording in S.590 is such that equivalency would not be granted unless an organization were capable of providing universal on-site and blind proficiency testing to all regulated laboratories. In other words, it is an all or none situation. Because of what we believe to be the prohibitive costs associated with operating blind and/or on-site proficiency testing, it will be most difficult to meet these requirements. Thus a program which we believe has benefited the laboratory practitioner, the

patient, and the government, may, by necessity, end.

We therefor urge that language be included in either the bill or the Committee Report, giving the Secretary flexibility in granting equivalency to nonprofit organizations which would remove the "all or none" implication.

Our understanding of the term "enter into agreement with" in this section will permit the Secretary and the states to utilize the programs of qualified nonprofit entities as an alternative to federal and state programs.

From the Committee Report on S.1737 (page 18), "The Committee is aware of the role that certain nationally recognized private nonprofit entities have played in the improvement of laboratory testing .... Thus, this legislation provides that the Secretary, or a State which has met or exceeded federal standards, may enter into arrangements with qualified private non-profit professional testing services . . . . the programs of those qualified national organizations which meet or exceed the standards developed by the Secretary would be acceptable for meeting Federal and/or State laboratory licensing requirements, and the government could enter into appropriate arrangements with such entities."

Our experience since 1967 has shown that the concept of equivalency works. Equivalency has provided, and will continue to provide, a mechanism for coordinating the complementary roles of regulatory agencies and professional organizations in safeguarding the public interest. The College is justifiably proud of its programs which have been granted equivalency.

We would also note that the Board of Registry of the American Society of Clinical Pathologists has for many years been a leader in the certification of clinical laboratory personnel. The ASCP and its

program should be recognized as an organization providing services equivalent to those required by federal standards.

We are somewhat concerned over the wording in subsection (b). We believe it appropriate that a phrase be added to that subsection to provide for the state to enter into agreements (for inspection, proficiency testing, and personnel certification purposes) with qualified nonprofit entities which have adopted standards at least as stringent as federal standards.

Licences: Section 3 (Section 371 (c)(2) and Prohibited Acts:

Remedies: Section 375

The College agrees that those that violate the law or fail to comply with the standards under the law should receive appropriate disciplinary actions.

We believe it most important that those sections cited above which deal with penalties for improper or unlawful actions be very clear that such actions are violations only when conducted in a knowing and willful manner. This clear language would protect the employee of a laboratory from criminal penalty for performing acts which he/she has been instructed to perform. It would also protect the laboratory owner, operator or director from criminal penalty for acts performed by their employees of which they are unaware and which violate the law.

Employee Protection: Section 375 (c)

The College must question the need for a special provision to provide protection for laboratory personnel. This provision will make it difficult to separate an incompetent employee. Moreover, we are unaware of any evidence to suggest that there is a widespread problem

that warrants special federal mandate.

We must ask; Is an allocation of a very few cases of an employee of a clinical laboratory being discharged for testifying reason to mandate a complex system of redress for employees? We do not believe it to be.

The CAP has long supported the concept of making available high quality, reliable laboratory service to all segments of the public served by pathology. For medical laboratory directors and personnel, this means provision of high quality laboratory results at a reasonable cost. A pathologist laboratory director must plan for and direct a diverse, complex laboratory operation in such different settings as the larger community hospital, the university or government institutions, the private laboratory, large or small, or the laboratory functioning primarily in research. His functions include the proper selection of instruments and methods during a time of knowledge explosion and rapidly changing technology. His performance must be quality conscious and rapid enough to meet both the demands of the consumer-physician who desires to have the latest tests available to solve patient care problems, and the patient-public which wishes the maximum of quality service at a reasonable cost.

Because of the very brief time span between introduction of S.590, hearings, and mark-up of the bill, we have not been able to address several sections of the bill that will not improve the quality of laboratory services. Thus, we request that our comments, on additional sections of S.590, which will be submitted at a later date, be considered by this Committee in its final deliberations on the bill.

We thank you for affording us the time to present our views on this important legislation.

STATEMENT OF

JEROME H. MODELL, M.D.

ON BEHALF OF

THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS,  
THE SOCIETY OF ACADEMIC ANESTHESIA CHAIRMEN,

AND

THE SOCIETY OF CRITICAL CARE MEDICINE

BEFORE THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

June 14, 1977

I appear before you today in my role as president of the Society of Academic Anesthesia Chairmen (SAAC) to testify regarding H.R. 6221. I have been requested by Dr. Richard Ament, president of the American Society of Anesthesiologists (ASA), and by Dr. Ake Grenvik, president of the Society of Critical Care Medicine (SCCM), to represent those groups as well.

The Society of Academic Anesthesia Chairmen (SAAC) is an organization comprised of the chairpersons of departments of anesthesiology in all the medical schools of the United States. Thus, the members of SAAC represent the entire community of anesthesiologists and related scientists who reside in medical school departments of anesthesiology and are responsible for clinical care, research, and education of physicians, nurses, and paramedical personnel within their area of expertise in those medical schools. The second group I represent, the American Society of Anesthesiologists (ASA), is a national medical organization of physicians having approximately 11,000 active members engaged in the practice of anesthesiology. The third group, the Society of Critical Care Medicine (SCCM), is oriented specifically to the care of the critically ill patient. Its membership consists of persons having an interest and demonstrated expertise in this field and at present numbers approximately 650.

In concept and in all major respects, SAAC, ASA, and SCCM favor adoption of H.R. 6221 as representing an intelligent step forward in the improvement of quality control in the clinical laboratories of the United States, and in the containment of costs associated with those laboratories. In the interest of proper, effective, and more economical patient care, however, we have three recommendations that we feel would improve and clarify the Bill.

1. Special-Purpose Laboratories. Subsection 353(b) of the Bill requires

that the Secretary of Health, Education, and Welfare promulgate national standards for all clinical laboratories, which standards will include requirements relating to quality control, facilities, periodic proficiency tests, and training and qualifications of laboratory personnel. The definition of clinical laboratories under subsection 353(a) is, of course, sufficiently broad to cover virtually any laboratory concerned with patient care, and we believe would be most commonly understood to apply to the multi-purpose clinical laboratories found both inside and outside hospitals.

In most major hospitals, however, there exists a number of single- or limited-purpose laboratories and highly specialized laboratories, the function or purpose of which is normally to analyze some particular body function or functions required immediately in connection with patient care. An excellent example of such a laboratory is a blood-gas laboratory, the purpose of which is to analyze a patient's blood for determining its relative acidity, its oxygen and carbon dioxide tensions, and related parameters. Although quality control is absolutely essential in such a laboratory, qualified persons can be taught to perform the tests, even though such persons do not have a background in the entire field of medical technology. It should be obvious that learning a limited number of techniques requires far less formal training than becoming proficient in analyzing the many parameters that might be found in a central or multi-purpose hospital laboratory.

A second example is the acute intensive care laboratory. Its purpose, in addition to analyzing blood for acidity and oxygen and carbon dioxide tensions, is to perform emergency tests required for the moment-to-moment care of critically ill patients. The speed necessary for obtaining such data usually precludes using the mass-produced or automated testing techniques common

to most multi-purpose laboratories. It is imperative that the data be accurate and available immediately, since the care of the critically ill patient must frequently be changed on a moment-to-moment basis if he is to survive. Of further importance is the fact that some parameters, such as the oxygen tension of blood, can change rapidly if there is any significant delay between the time of drawing the sample and the time that the oxygen tension is actually determined by suitable equipment. Thus, proximity of the laboratory to the areas of highest usage rate and recognition of the need for working rapidly by the persons collecting, transporting, and analyzing these blood samples is essential. This can best be assured by placing such a laboratory immediately adjacent to high usage areas, such as the intensive care unit or operating room, and by making the medical director of that unit responsible for its direction.

With reference to laboratories of these types, SAAC, ASA, and SCCM are concerned that upon passage of H.R. 6221, the Secretary may promulgate national standards entirely appropriate to a centralized multi-purpose hospital or independent laboratory, but which are unrealistic or unnecessary with respect to the single- or limited-purpose laboratory, or which render the cost of operating such a laboratory undesirable from the point of view of the patient, and ultimately from the point of view of the Federal Government as one of the principal payers of health care costs.

SAAC, ASA, and SCCM are aware of the provisions of subparagraph 353(b) (2) (C), which permit different standards depending upon the type of laboratory and the purposes it serves. It is suggested, however, that merely to include permissive language in this subparagraph is inappropriate, and that H.R. 6221 should mandate different standards depending upon the nature of the



laboratory involved. This can be accomplished by changing the word "may" to "shall" in this section of the Bill, as it appears on page 7, as follows:

"(C) Standards prescribed under subparagraph (A) for clinical laboratories [may] shall vary on the basis of the type of tests or other procedures or services performed by such laboratories or the purposes for which such tests, procedures, or services are performed.

Such a mandate should also be explained appropriately in the report of the Committee, possibly in the following terms:

The Committee recognizes that appropriate national standards for clinical laboratories will vary, depending upon the type of function or functions to be performed by the various laboratories in question. Standards appropriate to a central hospital laboratory or independent laboratory created and operated to perform a variety of procedures or services will not be appropriate to single- or limited-function laboratories created and operated to perform tests in connection with a particular kind of patient care. Examples of the latter types of laboratories are blood-gas laboratories and acute intensive care laboratories, normally located close to the actual site of patient care and normally operated by a licensed physician who may also be the medical director of the hospital's unit for that type of care.

2. Physician's Office Exemption. As you know, H.R. 6221 presently contains an exemption, under subparagraph 353(c) (2) (D), for clinical laboratories located in the office of a licensed physician. As you are also aware, the operating room, obstetrical suite, recovery room, and intensive care unit of

a hospital are; for all practical purposes, the "office" of an anesthesiologist. Reference to a physician's "office" under the current Medicare statute in connection with services incident to a physician's service has been construed by the Bureau of Health Insurance, in the case of an anesthesiologist, to relate to the hospital setting in which he performs his medical services. Similar reasoning would suggest that the "office" of the intensivist can properly be the hospital's intensive care unit. SAAC, ASA, and SCCM believe there would be considerable merit in clarifying this subparagraph of H.R. 6221, in order to make clear that the exemptions apply to the "office" of an anesthesiologist and intensivist. We would thus recommend that subsection (i) of subparagraph (D) be changed to read as follows, with a parallel change being made in subsection (ii):

"(D) (i) The national standards for clinical laboratories shall not apply to any clinical laboratory--

"(I) which is located in the office or ordinary place of medical practice of, and operated by, a licensed physician, dentist, or podiatrist, or a group of such practitioners, and

"(II) in which the only tests or procedures which are performed are tests or procedures performed by such a practitioner [in connection with] as an adjunct to the treatment of his patients.

SAAC, ASA, and SCCM believe that this amendment would represent an appropriate clarification of the "office" clinical laboratory without in any way detracting from the basic purpose of H.R. 6221.

Should the rationale and importance of such designation be unfamiliar to any Committee member, I will explain further. The anesthesiologist and the

intensivist, in the routine care of their patients, must analyze biophysical and biochemical data on a moment-to-moment basis and, based on this data, must apply the necessary therapy. Some examples would include, among others, continuous beat-by-beat function of the heart, breath-by-breath analysis of exhaled gas, beat-by-beat analysis of the configuration of arterial pressure waves, constant monitoring of the inspired oxygen concentration, and determinations of cardiac output. These tests are all done at the patient's bedside or operating room table, as appropriate. The nature of the tests and the speed with which therapy must be applied if changes occur precludes either transmitting the data to any other "central laboratory" or consulting with any other "laboratory director". Furthermore, feeding this information into a central area and having an analysis returned would necessitate a very expensive system of telemetry and computerization that is at the present time neither available nor necessary in most hospitals.

Second, we suggest changing the words "in connection with" to the phrase "as an adjunct to" so that it would be possible to exempt as a physician's "office" that area and those physicians that directly prescribe therapy on a moment-to-moment basis, as opposed to those who use the tests for diagnosis only and then refer patients to other physicians for therapy. With this alteration in language, we believe it would be possible to accomplish our goal of continued excellence in patient care without creating as an "office exemption" the offices and laboratories of all physicians.

We believe that the Committee report should contain language making the previously mentioned points. Such a modification would have the effect of assuring that the anesthesiologist and the intensivist could monitor their patients on a moment-to-moment basis, through the use of analytical equipment

located in the operating room, recovery room, or intensive care unit, without the necessity of their being forced to register themselves as a "clinical laboratory" under H.R. 6221. This would permit them to make the necessary adjustments in the care of their patients. One suggestion for such language would be the following:

The Committee recognizes that for some physicians, such as the anesthesiologist and the intensivist, the "office" is a special area within a hospital. In the case of the anesthesiologist, this would be the operating room, the obstetric suite, the recovery room, and the intensive care unit; in the case of the intensivist, it would be the intensive care unit. It is essential that these physicians be permitted to analyze biophysical and biochemical data relating to their patient on a moment-to-moment basis in order to alter therapy as appropriate. The Committee recognizes that this is essential and, therefore, wishes the term "office" to be expanded to include "the ordinary place of medical practice of" the physician whenever the tests performed are used as an adjunct to the treatment of his patient.

3. Experimental Laboratories. Unlike the Senate version of the Clinical Laboratories Improvement Act, H.R. 6221 states that the Secretary may exempt from the national standards for clinical laboratories any laboratory in which the only tests or procedures which are performed are tests or procedures for research (other than research to determine the course of treatment for an individual patient) section 353 (2) (D) (iv). The Senate version permits exemption, on application, for research laboratories engaged primarily in research.

SAAC, ASA; and SCCM feel that there are certain types of tests which, because of their complexity, rarity of need and, therefore, relatively high cost of maintaining test facilities, can be performed only in laboratories that are maintained primarily for purposes of research. The "individual patient" exemption contained in H.R. 6221 will not, it is believed, permit research laboratories offering such a rare test for the benefit of any patient to obtain exemption from the national standards requirements. If this interpretation is correct, H.R. 6221 will preclude the physician from confirming diagnosis of rare or uncommon diseases for which the appropriate tests are not available in most laboratories. It is well known, for example, that the definitive tests necessary to diagnose such rare disorders as malignant hyperthermia and atypical pseudocholinesterase are available in only a handful of research laboratories in the United States. It is essential that our patients and their physicians be permitted to take advantage of such laboratories.

On the other hand, we understand the concern of the Committee that merely changing the language to coincide with the Senate version of the Bill might lead to abuse. For example, a laboratory that is operated 51 percent for research purposes and 49 percent for "routine" clinical work could be exempt and, therefore, use this loophole to fund their research laboratory through payment for clinical tests. This would defeat the purpose of H.R. 6221. If the Committee wishes to adopt the language in the Senate version of the Bill, we believe that this loophole could be plugged by appropriate language in the Committee report, such as the following:

The Committee recognizes the fact that there are some laboratory tests that, because of their complexity and rarity

of need, can be performed economically only in laboratories that are maintained primarily for purposes of research. The Committee wishes to exempt, on application, those tests within such research laboratories, since they fulfill a national need that is not available through routine channels. The Committee cautions the Secretary, however, that it does not condone a situation in which a laboratory, normally used primarily for research, performs a significant number of "routine" laboratory tests, thereby using its research designation to avoid conforming to the law.

An alternate approach would be to amend H.R. 6221 section 353 (2) (D) (iv) found on lines 19-24, page 12, in the following terms:

"(iv) The Secretary shall, upon application, exempt, on such terms and conditions as may be appropriate, from the national standards for clinical laboratories any laboratory in which the only tests or procedures which are performed are tests or procedures for research or for the analysis or diagnosis of rare disorders [(other than research to determine the course of treatment for an individual patient)].

#### SUMMARY

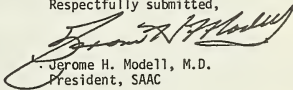
In concept and in all major aspects, SAAC, ASA, and SCCM favor the adoption of H.R. 6221 as representing an intelligent step forward in the improvement of quality control in the clinical laboratories of the United States and in the containment of costs associated with these laboratories. This statement

is made assuming the following clarifications are adopted:

1. That the Secretary shall promulgate national standards that recognize the different natures of laboratories created to serve specific purposes.
2. That the "office" of the anesthesiologist and the intensivist includes "his ordinary place of medical practice", namely, the operating room, obstetric suite, recovery room, and intensive care unit, as appropriate.
3. That extremely complex or rare tests performed in research laboratories which perform such tests for the diagnosis of rare disorders should be exempted, on application, by the Secretary, thus permitting the results of such tests to be used in patient care.

I appreciate the opportunity to share my views, on behalf of SAAC, ASA, and SCCM, with you. Thank you.

Respectfully submitted,



Jerome H. Modell, M.D.  
President, SAAC

JHM:ps

## SQUIRE, SANDERS &amp; DEMPSEY

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March 16, 1979

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1050 BRUSSELS, BELGIUM

The Honorable Herman E. Talmadge  
109 Russell Senate Office Building  
Washington, D. C. 20510

Dear Senator Talmadge:

In anticipation of early hearings on S.505, introduced earlier this month by you and Senator Dole, we have been asked by the American Society of Anesthesiologists (ASA) — for which we act as legal counsel — to submit the following views for inclusion in the record.

As you know, ASA has previously testified in favor of certain substantive provisions of the Bill relating to definition of the reimbursement standards for anesthesiology services. While these provisions have been changed in certain minor and clarifying detail (Section 6(a) (2) of S.505), ASA continues to find these provisions satisfactory and reflective of sound medical practice.\*

In the past few months, we have discussed with members of the Finance Committee staff certain additional clarifications which, although not practical for inclusion in the language of the Bill, nonetheless in ASA's judgment are required for a proper understanding of legislative intent. We have been requested by the staff to prepare proposed clarifying language for inclusion in any Committee Report on the Bill. We thus offer the following for the Committee's consideration:

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\*We note that these provisions are not included in that portion of the S.590, Clinical Laboratories Improvement Act of 1979 (introduced by Senator Javits on March 8, 1979) dealing with physician reimbursement principles. While ASA does not oppose these provisions in S.590, we strongly urge that if the Senate is going to deal with physician reimbursement principles, whether under S.590 or S.505, the entire provision on this subject of S.505 should be included. As you know, the provisions of S.505 dealing with anesthesiology services have been constructed with some care and have involved close consultation among ASA, the Finance Committee staff, and representatives of Medicare. The foreshortened provisions of S.590, if adopted, simply would not reflect the detailed understandings that have emerged from prior consultations on the predecessors to S.505.



## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Herman E. Talmadge

March 16, 1979

Page Two

Section 6(a)(1) of the Bill provides for the exclusion from Medicare Part B reimbursement of services performed by a physician "as an educator, and executive, or a researcher; or any professional patient care service" not involving personal performance or direction by a physician, for the benefit of a patient. It is not the intent of the Committee, by this language, to exclude from Part B reimbursement those services of a physician involving his personal performance or personal direction for the benefit of a patient, when simultaneously with performing those services, the physician is also engaging in a teaching function for others (e.g., resident physicians not in his employ) who are also participating in or observing the services as part of their educational experience.

Section 6(a)(2) of the Bill provides additional standards to the Act to govern Part B reimbursement for services by an anesthesiologist, in general limiting such reimbursement to those instances in which the physician either personally performs or personally directs the provision of anesthesia care in connection with surgical or obstetrical procedures. The Committee recognizes that anesthesiologists perform medical services to patients outside the context of a surgical or obstetrical procedure, and it is not the Committee's intent to affect reimbursement standards in these other contexts. The Committee also recognizes that many anesthesiologists practice in partnership or "group" form, and that more than one member of the group may permissibly provide the required services for which reimbursement is authorized, e.g., one physician in the group may make the pre-anesthetic evaluation, while another may actually anesthetize the patient.

ASA wishes also to state its support for the principles of Section 9 of the Bill, which create an express statutory basis under Medicare for rendition of surgical services in an ambulatory center. In point of fact, a large number of these centers have been established on the initiative of anesthesiologists. Many ASA members believe that these centers are to be strongly encouraged as a vehicle for rendition of surgical and anesthesia care, in proper cases, at a lesser facility-operation cost than that normally involved in a hospital setting. ASA

## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Herman E. Talmadge

March 16, 1979

Page Three

believes, however, that Section 9 is not presently clear that two alternative means are to exist for reimbursement of an anesthesiologist or other non-surgeon physician who performs services in connection with a surgical procedure in such a center -- either by participating (by agreement) in an all-inclusive fee paid to the center, or by separate normal Part B reimbursement. We respectfully recommend that these alternatives be spelled out in the report of the Committee on S.505.

We have also been asked by ASA to reiterate its opposition to Section 7 of S.505, as currently drawn. ASA's objection to this provision is that it unduly and improperly limits the participation of a physician organization, in the development of a relative value schedule, to reacting to proposals by the Secretary. ASA believes that such a limitation erodes its constitutional right to petition the Government, a right which is confirmed in the decisions of Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); and United Mine Workers v. Pennington, 381 U.S. 657 (1965).

In this connection, we respectfully refer you to the terms of a Consent Order recently entered into between ASA and the Federal Trade Commission (relating to ASA conditioning membership privileges on the mode of compensation received by a physician) which states as follows:

It is further ordered, That nothing in this order shall prohibit or limit the organizations and persons subject to this order from petitioning the government for a redress of grievances by:

A. Preparing or furnishing testimony, information, or advice to, or negotiating with, any government body or agency or furnishing drafts thereof to any organization which is preparing or furnishing testimony, information or advice to, or negotiating with, any government body or agency with respect to the same subject matter;

B. Advising its members and others of legislation, programs, policies, regulations, procedures, or interpretations of any government body or agency and soliciting their views thereon;

C. Informing members and others of any testimony, information or advice supplied to, or negotiations with, any government body or agency; and

D. Suggesting or recommending that members or others undertake the activities enumerated in subparagraphs (A), (B), and (C) above;

## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Herman E. Talmadge  
March 16, 1979  
Page Four

but only as long as the activities enumerated in this part VI are not undertaken with the purpose or intent of achieving a result prohibited by part II of this order through means other than the action of a government body or agency.

We do not believe that the philosophical approach of Section 7 adequately recognizes the rights of organized medicine to initiate negotiations with the Secretary, concerning relative value schedules or other subjects of common concern.

We request that a copy of this letter be included in the record of the Subcommittee's hearings on S.505.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Michael Scott".

Michael Scott

## SQUIRE SANDERS &amp; DEMPSEY

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March 19, 1979

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CSC BRUSSELS, BELGIUM

The Honorable Jacob K. Javits  
321 Russell Senate Office Building  
Washington, D. C. 20510

Re: S. 590 - Clinical Laboratory  
Improvement Act of 1979

Dear Senator Javits:

I am writing to you in our capacity as legal counsel for the American Society of Anesthesiologists (ASA). ASA, a national medical organization of some 11,000 physicians specializing in the practice of anesthesiology, has asked us to offer the following comments on S. 590.

In concept, ASA favors the adoption of S. 590 (as it did the predecessors thereto) as a means to improve quality control in clinical laboratories and to contain associated costs. In the last session, Dr. Jerome Modell, Chairman of ASA's Committee on Governmental Affairs, testified -- on behalf of ASA, the Society of Academic Anesthesia Chairmen, and the Society of Critical Care Medicine -- in favor of H.R. 6021 (Clinical Laboratories Improvement Act of 1978) before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce. A copy of his prepared statement is enclosed for your review. As noted in Dr. Modell's statement to the House Subcommittee, there are -- from the point of view of proper anesthesia care -- a number of clarifications which, in ASA's judgment, materially improve and clarify the legislative proposals on clinical laboratory regulation, as set forth both in the bills before the Senate and House in the last session, and in S. 590.

1. Special-Purpose Laboratories. Subsection 372(c) of S. 590 provides that national standards prescribed under subsection 372(b) for clinical laboratories "may" vary on the basis of the type or purpose of

## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Jacob K. Javits  
March 19, 1979  
Page Two

the tests, procedures, or services performed. ASA is concerned that inclusion of such permissive language does not adequately assure that there actually will be different standards promulgated depending upon the nature of the laboratory involved.

The definition of "clinical laboratory" under subsection 370(1) is broad enough to cover virtually any laboratory concerned with patient care. In most major hospitals, however, there exist as well as "normal" multi-purpose clinical laboratories, a number of single- or limited-purpose highly specialized laboratories which are operated by a physician independent of the multi-purpose laboratory. These latter laboratories are used to analyze some particular bodily function or functions required immediately in connection with patient care. Because of the importance of accurately monitoring moment-to-moment changes in certain aspects of a patient's functions, these laboratories are usually located immediately adjacent to high usage areas, such as the operating room. Examples of such types of laboratories are the blood-gas laboratory, used to analyze a patient's blood for determining its relative acidity and oxygen and carbon dioxide tensions, and the acute intensive care laboratory, used to analyze blood and to perform emergency tests required for care of critically ill patients.

In the blood-gas laboratory, qualified persons can be taught to perform the limited number of techniques necessary with far less training than is required for proficiency in performing the varied tests and analyzing the many parameters that might be found in a multi-purpose hospital laboratory. Similarly, in the acute intensive care laboratory, the speed necessary for obtaining the data usually precludes using the testing techniques common to most multi-purpose laboratories.

ASA is concerned that the national standards promulgated, while they may be entirely appropriate for centralized multi-purpose hospital or independent laboratories, may be unrealistic or unnecessary in terms of operation and expense with respect to the single-purpose laboratory. Therefore, ASA proposes that the word "may" be changed to "shall" in subsection 372(c) as it appears on page 10, line 9:

(c) Standards prescribed under subsection (b) for clinical laboratories [may] shall vary on the basis of the type of tests, procedures, or services performed by such laboratories or the purpose for which such tests, procedures, or services are performed.

## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Jacob K. Javits  
 March 19, 1979  
 Page Three

This mandate to the Secretary should also be explained appropriately in the report of the Committee. ASA recommends for your consideration in this respect the proposed language on page 4 of Dr. Modell's statement.

2. Physician's Office Exemption. ASA is pleased to note that S. 590 retains the concept of physician office exemption contained in the 1978 bills, but is deeply concerned that the language of S. 590 will be interpreted, literally, as permitting an exemption only as to laboratories in a physician's office "physically" operated by the physician himself, as distinct from non-physician personnel in his employ and under his direction. ASA recommends that the language of subsection 372(f) (3) (A) (i) be changed to read:

(i) which is located in the office of, and operated by or under the direction of, a licensed physician, dentist. . . .

ASA is particularly interested in this provision of the Bill, inasmuch as the operating room, obstetrical suite, recovery room, and intensive care unit of a hospital are, for all practical purposes, the working "office" of an anesthesiologist. In fact, the Bureau of Health Insurance has construed "office" for certain purposes under the Medicare statute to relate to the hospital setting in which an anesthesiologist performs his medical services.

ASA therefore recommends that subsection 372(f) (3) (A) (i) at page 12, line 18, be further changed to read as follows:

(3) (A) Upon such conditions as the Secretary may by regulation prescribe, the Secretary may exempt from the national standards for clinical laboratories any clinical laboratory --

(i) which is located in the office or ordinary place of medical practice of, and operated by or under the direction of, a licensed physician. . . .

ASA would also suggest changing the words "in connection with" in subsection 372(f) (3) (A) (ii) at page 13, line 6, to the phrase "as an adjunct to":

(ii) in which the only tests or procedures which are performed are routine tests or procedures (as determined by the Secretary) performed by such a practitioner or clinic [in connection with] as an adjunct to the treatment of the patients of such practitioner (or practitioners) or clinic.

## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Jacob K. Javits  
March 19, 1979  
Page Four

ASA believes that these modifications would have the effect of assuring that anesthesiologists can monitor patients on a moment-to-moment basis through the use of equipment located in the operating room, recovery room, or critical care unit, without the necessity for such activities being subject to the national standards.

It would also be helpful if the Committee's report contained language clarifying this point, and ASA recommends to your attention the language suggested by Dr. Modell at page 7 of his statement, and to the responsive language actually contained in H.R. Report No. 95-1004, Part I at page 17:

The Secretary may need to exercise flexibility in what he determines constitutes a physician's office. For example, some physicians perform tests while treating their patients in a special area within a hospital. In the case of the anesthesiologist, this would be the operating room, the obstetric suite, the recovery room, and the intensive care unit; in the case of the intensivist, it would be the intensive care unit. It is essential that these physicians be permitted to analyze biophysical and biochemical data relating to their patient on a moment-to-moment basis in order to alter therapy as appropriate.

3. Experimental Laboratories. ASA endorses the language of subsection 372(f)(3)(D) at page 14, line 3, exempting from the national standards those laboratories in which certain types of rare and/or complex diagnostic tests for rare disorders are performed. As the drafters of this legislation have recognized, it is essential that patients and physicians be permitted to take advantage of such laboratories. In this connection, I draw your attention to that portion of Dr. Modell's attached statement dealing with experimental laboratories, in which he comments favorably on the approach now taken in S. 590.

4. Physician Reimbursement. Consistent with its prior positions on proposed legislation introduced in recent years by Senator Talmadge, ASA does not oppose the principles set forth in Section 7 of S. 590 -- dealing with physician reimbursement under Medicare Part B. ASA points out, however, that unlike Senator Talmadge's current Bill (S. 505), S. 590 does not deal in specific terms with reimbursement principles relating to anesthesia care. ASA respectfully refers you to the

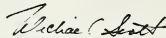
## SQUIRE, SANDERS &amp; DEMPSEY

The Honorable Jacob K. Javits  
March 19, 1979  
Page Five

fact that the principles on reimbursement for anesthesia care, set forth in S. 505, have been rather carefully worked out, over a period of many months, as a result of consultations among the Senate Finance Committee, ASA and representatives of the Bureau of Health Insurance. In this connection, ASA attaches hereto its letter of comment on S. 505, and respectfully urges that your Committee consult with the Senate Finance Committee on these matters, before reporting out a bill which would include Section 7.

I appreciate your consideration of these comments and request that they be included in the record of these hearings. If the ASA can be of assistance in providing further background information or answering questions raised by these comments, please feel free to contact me.

Respectfully submitted,



Michael Scott

Enclosures

cc: The Honorable Edward M. Kennedy, Chairman  
    Subcommittee on Health & Scientific Research  
    Senate Committee on Human Resources  
    Robert Wenger, Professional Staff Member  
    John Rother, Professional Staff Member



Testimony

by

Albert A. Dietz, Ph.D.

President

AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY

In Consideration of

S. 590

CLINICAL LABORATORY IMPROVEMENT ACT OF 1979

Senate Labor & Human Resources Committee

Sub-Committee on Health

United States Senate

March, 1979

The American Association for Clinical Chemistry (AACC) is most pleased to provide the Committee with the Association's views on major provisions included in the Clinical Laboratory Improvement Act of 1979, S. 590.

The AACC is a national professional organization, representing nearly 5,000 members engaged in the delivery of clinical laboratory services. The Association's membership is comprised of clinical chemists at the doctoral, master's and bachelor's degree levels of education. A majority of our members are individuals at the doctoral and master's degree level in science or medicine. Most of the bachelor's level members have their degrees in chemistry. At the advanced degree level, many specialty disciplines are represented, including: analytical chemistry, physical chemistry, biochemistry, toxicology, pharmacology, pathology, and geriatrics.

The primary professional interest of the AACC membership is the application of the science of chemistry to the diagnosis and treatment of disease and the assessment of patient health. The AACC membership represents an important scientific resource for improving the quality of clinical chemistry testing, clinical laboratory services, and their impact on the quality of health care delivered to the public. In that regard, over 50 percent of all clinical laboratory tests performed in this country are clinical chemistry tests.

The reintroduction of clinical laboratory improvement legislation into the 96th Congress once again provides the opportunity to insure that

quality laboratory services are available to all Americans. In this regard, the AACC is pleased to endorse the intent of S. 590 and the important objectives to which it is dedicated.

Specifically:

1. Regulations and Licensing of Clinical Laboratories

The AACC believes it is essential that the public interest and welfare be protected by requiring that all clinical laboratories comply with uniform national standards to assure accurate and reliable testing. The application of these standards should include all facilities examining materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the assessment of human health. Specifically:

1. Physician's Offices

Physician offices, irrespective of size or location, which perform tests used in the diagnosis of patient health, should be required to meet the national standards as will be established under this proposed legislation.

2. Rural Health Facilities

The definition of a rural health facility should include laboratories in small rural hospitals (50 beds or less) and the branch or satellite public health laboratory employing three persons or less. The question here is the type of services provided rather than the location of the facility.

The following facts should be considered:

It is unrealistic to expect the volume or scope of work to be enough to attract or justify the employment of a fulltime laboratory director, as such.

The procedures employed should be limited to basic and simple techniques. The more complicated laboratory work should be referred to a larger laboratory.

Qualified consultants with defined duties can be obtained at far less cost than directors to provide technical expertise for smaller, less sophisticated facilities.

Under these circumstances, the presence of a qualified technologist is essential and cannot be waived.

General day-to-day administration in these facilities can be provided by other than qualified scientific, technical personnel because of the limited nature of the services offered.

Adherence to National Standards:

Rural health facilities as defined above, should be required to comply with national standards.

3. Research Laboratories/Insurance Laboratories

The AACC recommends that these laboratories (industrial hygiene or specialty labs) irrespective of methods of reimbursement or

funding support, which perform tests used directly in patient diagnosis and treatment be required to comply with national standards.

II. Enforcement of National Standards

1. Office of Clinical Laboratories

As was pointed out earlier, the AACC endorses the basic intent of proposed CLIA legislation aimed at improving the quality of laboratory performance by extending existing regulatory authority and licensing requirements for clinical laboratories.

In this regard, the Association believes that the most effective way to insure compliance with uniform national standards is through the establishment of an Office of Clinical Laboratories (OCL) charged with the responsibility for coordinating all federal activities relative to the clinical laboratory field. With this in mind, the identification of a Director of Clinical Laboratories as considered in S. 590 does not go far enough in insuring this consistency of lab oversight.

The major problem with existing law is the lack of uniform national standards for all laboratories along with the inadequate coordination of federal policies. These facts have resulted in duplication and multiplicity of administration over laboratories in a variety of settings.

In addition, HEW's recent mishaps in the development of proposed uniform national standards for clinical laboratory personnel (under consideration for nearly four years) further indicates the inability of existing regulatory structure and authority to deal with the oversight and to develop federal laboratory policy.

2. Inspection Authority

The AACC supports the need for regular inspections of clinical laboratories as a means to insure that the quality of testing being performed is consistent with nationally established standards. Furthermore, the AACC believes that occasional and unannounced inspections are essential to proper enforcement of national standards.

3. National Advisory Council

The AACC strongly supports the need for the establishment of a National Advisory Council to the OCL or Director of Clinical Labs. In order to provide the OCL with the professional expertise necessary to develop and implement appropriate standards, an advisory council composed of professionals practicing in the field is essential.

4. Oversight Responsibility

The AACC strongly endorses the need for states to undertake the regulation of clinical laboratories within their jurisdiction, provided that these states adopt standards which are no less stringent than the uniform national standards as established under the proposed legislation.

In this regard, and in order to encourage states to assume this "right," appropriate "startup" funds should be made available from the federal government to those states requesting such support.

### III. Personnel Standards

#### 1. Preamble

Uniform national personnel standards are necessary for all levels of clinical laboratory practioners who exercise an appreciable degree of independent thought and action in the performance of their duties. In addition, national standards must be flexible enough to allow for various types of organizational structures and laboratory administration. This is necessary due to the rapid expansion of the science of medical laboratory testing and technology which has led to a new type of specialist in the field. This trend towards specialization, both in terms of instrumentation as well as the professional working in the field, has lead to greatly improved patient testing and care at reduced costs.

For example, the doctoral scientist who is a board eligible specialist in clinical chemistry or clinical microbiology is qualified to direct a specialty laboratory in their discipline. This scientist may be directly responsible to

the medical governing board of their institution for clinical relevance of patient care results from their laboratory, rather than through traditional modes of organization which channels lines of responsibility through a clinical laboratory director.

The AACC believes strongly that an active partnership in clinical laboratory quality assurance between the patient's physician and the scientific or technical laboratory director is the patient's best protection against inaccurate laboratory results.

In order to insure that laboratory testing is accurate and reliable, appropriate uniform national standards for clinical laboratory personnel must be developed. These standards should be prepared in such a way as to insure the necessary mix of educational achievement and practical experience for each level of responsibility in the laboratory. Only in this way can we assure the proficiency of personnel. Experience alone cannot be an adequate measure for the needed competence.

Finally, we strongly resist the addition of detailed regulations above these minimal standards, e.g., detailed listing of dates, proficiency testing examination of personnel, too restrictive educational standards, etc., that unnecessarily limit the flexibility of control by the local medical community and also add



unnecessary costs to the operation of the laboratory. The personnel standards described below attempt to meet all of these criteria.

2. Who Will Prescribe Standards

Specific levels of personnel, i.e., Director, Chief Technologist, etc., to be required by law to have personnel standards established for them by the Secretary of HEW in consultation with OCL and the National Advisory Council (unless specifically referred to in this Bill, it is the AACC's concern that the DHEW will continue to back away from establishing national uniform standards for the appropriate levels of clinical laboratory personnel).

3. Standards Should be Prescribed for the Following levels of Laboratory Personnel

Director of Clinical Laboratories  
Scientific (or Technical) Director  
Chief Technologist  
Medical Technologist

4. Specific Qualification Standards

General Concerns:

The AACC supports the concept of upward mobility in the clinical laboratory but we must stress the need for additional and continuing education, not just experience, if the individual is to be prepared to assume responsibility for procedures which can determine the life and death of another individual. For each progressive increase

in levels of responsibility, an increase in formal education is required. There can be no professional growth without continuing education for the career professional in the scientific and technical health disciplines. Every effort must be made to stimulate and assist individuals in their career development.

Continuing competence would be assured more by providing continuing education than by using examinations as a determinant. Past experience indicates that it would be wiser to spend money for continuing education and training than to attempt to prove continued competence by a system of examinations.

In terms of "grandfathering" of personnel, the AACC supports the concept of grandfathering on a onetime, specified cutoff date basis. The purpose here is to protect the public-at-large by assuring that after a given point in time only persons having defined qualifications may perform certain functions.

Specifically:

- A. Director of Clinical Laboratories (oversees all clinical laboratory activities multi-disciplinary)

Doctoral Degree (Basic Science, i.e., chemistry, biology, medicine or equivalent) who is trained in a clinical laboratory specialty and is Board certified or eligible in one of these specialties;

(i.e., the American Board of Clinical Chemistry (ABCC), the American Board of Medical Microbiology (ABMM), American Board of Pathology (ABP), etc. Please note, these Boards are specifically referred to and accepted in regulations prescribed under Medicare 1965 and CLIA 1967 Laws).

- B. Scientific Director (In those facilities whose size and scope of Services is sufficient to require an individual in each specialty lab to act as its director).

Doctoral Degree (Basic Science, i.e., chemistry, biology, medicine, or equivalent) who is trained in a clinical laboratory specialty and is Board certified or eligible in one of these specialties, or

Master of Science in appropriate discipline, plus appropriate training which includes 30 academic graduate credits in clinical laboratory sciences and have 6 years of clinical laboratory experience, 4 years of which must have been at the supervisory level.

- C. Chief Technologist

Doctoral Degree (Basic Science, i.e., chemistry, biology, medicine, or equivalent) who is trained in a clinical laboratory specialty and is Board certified or eligible in one of these specialties, or

Master of Science in appropriate discipline, plus appropriate training which includes 30 academic graduate credits in clinical laboratory sciences and have 6 years of clinical laboratory experience, 4 years of which must have been at the supervisory level, or

Have an earned master's degree with at least 15 graduate-level academic courses in related work to the specialty area and have two years of experience in the area, or

Have earned bachelor's degree with a major in a biological or chemical science, or in medical technology, plus 15 graduate-level semester hours in course related work to specialty, plus 5 years of experience in that specialty.

D. Medical Technologist

(A technologist may be qualified as a specialist or medical technologist).

Medical Technologist Qualifications

All of those listed for Chief Technologist, as well as:

B.S., in M.T., including 12 months of clinical education or experience; or,

90 semester hours in accredited college and 12 additional months of appropriate clinical education or practical experience; or,

10 years pertinent full-time clinical laboratory experience prior to effective date of regulations and employed in clinical laboratory for at least 2 of last 5 years; or,

Specialty Medical Technologist

All of those options listed above, except that the clinical experience and/or educational training must have been acquired in the appropriate specialty in which that individual plans to work.

- IV. Finally, the AACC recommends that the following subjects be considered for in-depth study as they relate to this Bill's overall objective:

"Study of Requirements for Laboratories and Laboratory Personnel"

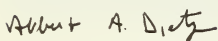
"Study of Financial Arrangements made by hospitals for clinical laboratory services"

"Federal funding for advancing clinical laboratory services" (specifically applied research)

"Federal funding for advanced training and continued competence of clinical laboratory personnel"

The AACC commends you on your continued leadership in this important area and appreciates this opportunity to present you with our views.

Respectfully submitted,

A handwritten signature in dark ink, reading "Albert A. Dietz". The signature is fluid and cursive, with the first name "Albert" and last name "Dietz" clearly legible.

Albert A. Dietz, Ph.D.  
President  
AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY  
1725 K Street, N.W.  
Washington, DC 20006

AAD/KAB/bds

STATEMENT OF  
KATHLEEN D. SHEEKY, INFORMATION DIRECTOR  
CONSUMER FEDERATION OF AMERICA

BEFORE THE  
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
OF THE  
COMMITTEE ON HUMAN RESOURCES  
UNITED STATES SENATE

March 30, 1977

Consumer Federation of America is a federation of 220 national, state and local non-profit organizations that have joined together to espouse the consumer viewpoint. CFA and its member organizations represent over 30 million consumers throughout the United States. Among our members are Consumers Union, publisher of Consumer Reports, 17 cooperatives and credit union leagues; 45 state and local consumer organizations; 66 rural electric cooperatives; 27 national and regional organizations ranging from the National Board of the YWCA to the National Education Association; and 16 national labor organizations.

CFA applauds this Subcommittee for its expeditious reintroduction of the Clinical Laboratories Improvement Act.

Last year CFA submitted statements for the record in support of this legislation to this Subcommittee, as well as to the House Subcommittee on Health and Environment. As the bill was debated in the 94th Congress, we were joined by the following coalition in support of the strongest bill:

Amalgamated Meatcutters and Butcher Workmen  
American Association of Retired Persons  
Grover C. Bagby, Associate General Secretary, Board of Church and  
Society, United Methodist Church  
Communications Workers of America  
Cooperative League of the USA  
International Ladies' Garment Workers' Union  
International Union of Electrical, Radio and Machine Workers  
National Consumers Congress  
National Council of Senior Citizens  
Retired Employees Department, United Auto Workers of America  
United Auto Workers of America  
United Steelworkers of America

The arguments and examples set forth by us at that time still stand and our vigor for this legislation is now intensified. We fully share your longstanding concern regarding appropriate standards for our nation's clinical laboratories and are hopeful that successful passage of this legislation is now imminent.

At its most recent annual meeting on February 12, 1977, Consumer Federation of America's membership recognized that high standards of health care in this country cannot be achieved unless all clinical laboratories comply with uniform standards of performance both as to facilities and personnel. Accordingly, the membership overwhelmingly approved the following policy resolution:

*Clinical Laboratory Testing*—Consumers have a two-fold interest in establishing standards for clinical laboratory testing; health and cost. Of primary concern is the assurance of strict health and safety standards through reliable clinical testing results.

Consumers are alarmed at the evidence which demonstrates that laboratories including those regulated by Federal law have shocking error rates of most tests ranging from 20 percent to 50 percent. In addition to the human suffering resulting from inadequate clinical laboratory testing, the consumer is to bear the high cost of multiple and frequently unnecessary testing. Consumers pay \$8 billion annually for laboratory testing. There are often appalling price differences among laboratories for identical tests.

Accordingly, we urge legislation that would:

- a) Require licensing of all interstate and intrastate clinical laboratories, including independent hospitals and doctor office laboratories with collection including blood banks. Periodic quality spot checking should be required.
- b) Permit states to apply more stringent standards within allocated federal enforcement functions.
- c) Require disclosure by clinical laboratories of any contractual relationships with physicians, together with a posting of all fees for laboratory testing within local health planning units; and a mandatory itemization of costs on the physicians statement he or she bills for services performed.
- d) Require periodic examination of all operating personnel. HEW should be required to set up a coordinating unit for that purpose.
- e) Outlaw kickbacks.
- f) Require that advisory committees include an equitable number of bona fide consumer representatives.
- g) Require the establishment of standards of safe and efficacious methodology so that physicians in clinical laboratories have scientifically recognized evaluations of what tests should be conducted and under what circumstances. Accordingly, tests with marginal or no value should be eliminated.
- h) Encourage medical schools to offer comprehensive courses in clinical laboratory testing.



Without detracting from our support of the Clinical Laboratories Improvement Act of 1977 we would like to take this opportunity to urge you to strengthen the bill in several respects:

1. Reimbursement for Citizen Participation in Agency Proceedings.

Many citizens desire to participate in agency proceedings which have a direct or indirect impact on the health, safety, or economic well-being of themselves and other citizens. Unfortunately, the cost of such participation is usually prohibitively high. Considering the far-reaching impact of the many regulations that the Secretary is charged with promulgating under the proposed legislation, consumers have at once an obvious and substantial stake and contribution to make.

The requirements for reimbursement of such participation should be patterned after those set forth in S.270. These would preclude the awarding of such participation costs for those who do not make a substantial contribution to the proceedings, or do not have an economic interest that is relatively small in comparison to the cost of participation, or who would have the economic resources to participate effectively even without such an award.

2. Citizen Suits.

All too often, the vigorous enforcement of important health, safety, consumer, and environmental regulations is not even attempted when a particular administration is ideologically opposed to such measures. In exercising their discretion as government "prosecutors" and "enforcers" the federal agencies sometimes overlook many violations which the regulated interests would find expensive or bothersome to correct. But even under the most sympathetic and conscientious of administrations, government agencies cannot possibly be expected to monitor the potential violations of the mass of federal regulations. For example, in areas of massive unlawful racial discrimination such as in schooling, employment and

housing the government will never have the manpower, the techniques or the awareness necessary to enforce the law for all, no matter how hard it tries. Despite good intentions and dedication, the job is just too much to handle. Citizen watchdogs are needed to blow the whistle on violators, and to ensure that the will of Congress is enforced. Critics may claim that the costs of the measure will outweigh its benefits. Skeptics insist that frivolous suits will result. A citizen suits provision could be drafted to prevent this consequence from arising. There would be no provision for the award of damages to a successful plaintiff. Therefore, there would be no incentive to bring a suit for an economic windfall.

### 3. Standing.

Any person should be able to challenge the actions of the Office of Clinical Laboratories if it fails to comply with the laws of the United States. This could be accomplished by changing "person aggrieved" on page 21, line 18, to "person." It is hoped that this provision will increase the accountability of regulatory and administrative agencies, increase public confidence in the fairness of agency operations, and will allow interested persons to protect their interests from the effects of unlawful agency activities. Every citizen has the right to an honest, lawful government and every citizen is injured when unlawful government actions are allowed to persist. The injury is neither abstract nor speculative.

### 4. Records Available to the Public.

The ability of citizens to participate in government proceedings and judicial action relevant to this Act will depend in large part on their ability to have access to the relevant data filed with HEW by clinical laboratories. This could be accomplished by introduction of an amendment that would guarantee that access.

5. Overutilization and Duplication of Testing.

Evidence has been presented that two major causes of high-priced laboratory testing are overutilization or needless duplication in the acquisition of equipment. In order to recoup their investment in expensive, and often underused equipment, laboratories will run a large and often unnecessary series of laboratory tests. Consumers should not have to pay for such inefficiencies.

For example, a hospital may be planning to purchase a very expensive piece of equipment, when unbeknowns to it, that same equipment is owned by a nearby independent laboratory and is not being used to capacity. Under the present health planning system, Health Systems Agencies (HSA's) do not have jurisdiction over independent laboratories. As a result they cannot conduct comprehensive health planning of any given area and advise against imprudent investment in or utilization of laboratory equipment.

It is hoped that the original HSA legislation will eventually be amended so as to delete the exemption for independent laboratories. In the meantime we urge that laboratories be required to submit to the Secretary a statement of their policy and procedure for acquisition of major capital equipment, a list of such equipment purchased in the past year, and the number of hours the equipment is used directly related to the processing of specimens.

This requirement will be beneficial from many perspectives. First, it will indirectly force laboratories to take a close look at their purchasing policies and ultimate utilization. As a result, hopefully, they will be motivated to exercise prudence in such purchases and utilization. Secondly, it will provide information which can be of assistance in preparation of the report to be submitted to Congress on cost and pricing. Third, the information will be available to the public as a matter of record and could be scrutinized by individuals or groups which may desire to recommend methods of increased efficiency.

6. Evaluation of Automated Laboratory Equipment.

We are at a loss to understand why the Beall Amendment, which was adopted last year has not been included in S.705. That would enable HEW to evaluate and validate the accuracy, reliability and performance of laboratory testing equipment of clinical laboratories and make the results available to the public. This procedure would provide laboratories with much needed independent information about the performance standards and reliability of equipment they may be considering for purchase. It would undoubtedly lead to fewer purchases of (and hopefully production of) faulty or inadequate equipment and this will result in an enhancement of health care for consumers and a decrease in the cost of that care.

7. Division of Applied Research, Development and Dissemination.

Although the Clinical Laboratories Improvement Act of 1977 will extend, consolidate and coordinate the regulation of clinical laboratories in the nation, another dimension is also very much needed: the assurance of progress of the state-of-the-art itself. The improvement in laboratory methodology and utilization in medical practice can be assured by establishing an Applied Research, Development and Dissemination Division within the Office of Clinical Laboratories which the Act establishes.

The Division would provide a concerted program of applied research, development and diffusion for new methodologies and practices. Unless research and development efforts are promoted and supported for solving the rather mundane and pragmatic problems impeding the development of more accurate and more specific tests, many opportunities for improving the nation's health care will be lost.

Discussions on the need for regulatory reform always focus on the stagnation that too often develops in a regulatory agency. The Division of Applied Research and Development would help preclude that stagnation. As a logical complement to the regulatory function of the office, it would instill a continued fresh approach in

the area of clinical laboratory testing and improvement.

#### 8. Grant Program.

The goal of achieving improved methodology can never be realized unless there is adequate funding for appropriate research. Because the 14,000 clinical laboratories in this country are very diverse in terms of size, geography, etc., it makes sense to centralize the major research programs under the auspices of the federal government which can in turn disseminate the favorable results of that research for the benefit of all.

For these reasons we support inclusion of an amendment to authorize the Secretary to make grants to qualified laboratory scientists and practitioners for solicited and unsolicited proposals for applied research, development and dissemination studies and projects for improving laboratory methodology and utilization.

#### 9. State Advisory Councils.

Under the Clinical Laboratories Improvement Act of 1977 States assuming primary enforcement responsibility may adopt standards which differ from the national standards provided that these State standards are no less stringent than the national standards.

The Act intends that States assume a greater share of responsibility for assuring the accuracy and reliability of testing in the clinical laboratories within their jurisdictions. The public, therefore, must have a recognized role in advising, consulting with, and making recommendations to the State agency with respect to the implementation and administration of the primary enforcement responsibility, as well as with respect to the coordination of the State clinical laboratory regulatory program with the Federal program and the programs of neighboring states.

If the public viewpoint is to be adequately heard, it is essential that there be a significant number of public representatives on both the State advisory councils and the advisory council to the Secretary. Typically, public members on advisory councils are badly outnumbered. Consequently, they are more easily intimidated and carry little or no voting clout.

10. Expansion of Membership on the Secretary's Advisory Council.

In other sections of this Bill, significant differences between rural hospital laboratories, physicians' office laboratories and other types of laboratories are recognized and special provisions made. It is important, therefore, that these differences be assured a voice on the advisory council. Accordingly, we recommend that representatives of independent, hospital, rural, and physicians' office laboratories be included on the Secretary's Advisory Council.

11. Rural Study.

Section 3 of S.705 recognizes the existence of special problems with laboratory personnel qualifications in rural areas. Therefore, we recommend that the Secretary's Study Respecting Requirements for Laboratories and Laboratory Personnel in Section 6 should also examine the particular difficulties experienced by hospital clinical laboratories located in rural areas, in their hiring or training individuals to meet the standard qualifications, and identify how these problems may affect national standards.

Consumer Federation of America appreciates this opportunity to comment on S.705. This legislation is extremely important to American consumers, and will fill a large gap in federal regulation of medical services. We, therefore, urge your prompt and favorable consideration of this Bill.



# American Medical Technologists

BEFORE  
THE COMMITTEE ON LABOR AND HUMAN RESOURCES,  
U.S. SENATE  
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
HONORABLE EDWARD M. KENNEDY, CHAIRMAN,  
HOLDING HEARINGS ON S. 590, THE PROPOSED  
"CLINICAL LABORATORY IMPROVEMENT ACT OF 1979"

## STATEMENT OF THE AMERICAN MEDICAL TECHNOLOGISTS

This testimony is submitted on behalf of American Medical Technologists (AMT), a national registry and society of more than 12,000 qualified medical laboratory technologists and technicians headquartered at 710 Higgins Road, Park Ridge, Illinois.

The members of AMT are from varied backgrounds - colleges, Armed Forces schools, vocational schools - and they work in the laboratories of hospitals and clinics, federal and state installations, and in independent laboratories.

AMT was founded in 1939 and is the oldest and largest independent (that is, not owned by physicians) registry of laboratory technicians and technologists in the United States. It is an organization that has long been interested in adequate laboratory personnel standards and in standards

"Pride of the Profession"

Incorporated in 1939

for schools teaching such personnel and is itself a standards-setting organization for people staffing medical laboratories.

AMT is a registry, admission (membership) into which is gained only after the applicant proves proper training and experience and passes an examination. AMT is also the sponsor of the Accrediting Bureau of Health Education Schools (ABHES), an autonomous agency, which has been certified by the U.S. Office of Education as a nationally recognized accrediting agency. The Bureau has been accrediting schools and programs of education for laboratory technicians since 1964 and for medical assistants since 1971. The Bureau is the oldest technician-education accrediting agency and the first recognized by the Commissioner of Education in the field of laboratory technician education.

Over the years representatives of AMT and the Accrediting Bureau have worked with state and federal agencies, including the Department of Health, Education and Welfare and the Social Security Administration concerning standards for laboratory personnel. We believe that this exchange of views and data has contributed substantially to the field of public regulation of laboratories and we appreciate this current opportunity to present views on CLIA 1979.

While AMT certainly supports the general goals of S.590, as is evident through our membership in the National Coalition for CLIA which testified in support of the measure at hearings before the Subcommittee on March 16, 1979, we do regret the fact that the hearings have tended to focus entirely upon the existence of fraud and abuse and error rates in the nation's laboratories and have given little recognition to the good job which the great bulk of the thousands of laboratory personnel are doing.



Following are the views of AMT on specific provisions of S. 590.

We are glad to see that the legislation continues the requirement that personnel qualifications prescribed by the Secretary shall "not be limited solely to education requirements." Section 372(b)(4) now provides in pertinent part that national standards promulgated by the Secretary shall

To the extent necessary to insure the accuracy and reliability of the performance of tests and services by such laboratories, prescribe qualifications for directors and supervisory personnel of, and laboratory technical personnel employed in, such laboratories which qualifications shall (A) not be limited solely to education requirements but shall include, where appropriate, training, experience, and examination requirements. . .

It is our view, and we assume that of the Subcommittee, that this language requires that the Secretary will prescribe qualifications for laboratory technologists and technicians. It is imperative that this be made clear in the report language of the bill as it is apparently HEW's intent not to set standards for these categories of laboratory personnel. This was reflected in an HEW draft notice of proposed rulemaking and HEW is persisting in this view despite its conflict with past practice, actual health needs and substantial objections raised by informed and interested groups. Our objection to this HEW approach was expressed jointly with ASMT and ISCLT in a letter from the Coordinating Council of Clinical Laboratory Technologists (CCCLT) to HEW Secretary Califano dated February 9, 1979, a copy of which is attached for the Subcommittee's reference. Nevertheless apparently HEW continues in its view that regulation of technologists and technicians is not required and bases this in part on

its belief that the language of the bill providing that the Secretary prescribe personnel qualifications "to the extent necessary" gives HEW the flexibility to set no standards whatsoever for technicians and technologists. We are hopeful that the language of the Committee's report will disabuse HEW of this view.

With further regard to the language of Section 372(b)(4) we wish the Committee to make clear that the language of this Section does not represent a weakening of the relevant language of the earlier S. 705 (Section 353(b)(2)(A)(iv)) providing that the Secretary should set national standards:

To the extent necessary to insure the accuracy and reliability of performance of tests by such laboratories, prescribe qualifications for directors and supervisory personnel of such laboratories, laboratory technical personnel, and any other laboratory personnel, which qualifications shall (I) not be limited to education requirements but shall include as alternative requirements appropriate training, experience, and examination requirements. . .

We have been assured by the Subcommittee staff that the language of S. 590 providing instead that training, experience, and examination requirements be prescribed "where appropriate" and the elimination of the language of S. 705 stating that qualification standards not be limited to education requirements but shall include "as alternative requirements" appropriate training, experience and examination requirements is not intended to represent a dilution in the Committee's view that appropriate training, experience and examination standards should be developed as an adequate substitute for a strict education requirement in conformance with the language of S. Rep. No. 95-360, 95th Cong. 1st Sess. p. 17-18 stating:

While credentials and education generally correlate with performance, such an association is not absolute. There are numerous instances where persons with credentials cannot perform and where persons without credentials but with experience perform superbly. It was the committee's intent that personnel standards continue in use but the legislation specifically provides that training and experience may be substituted for education in setting standards for the laboratory personnel. This provision recognizes the fact that we face a critical shortage of all kinds of health manpower.

We trust that the above language of the Committee's report on S. 590 reflects the Committee's current views. AMT has long been an advocate of the need for recognition of suitable experience and demonstrated competence by laboratory personnel rather than the foreclosure of such personnel from placement and upward progression purely because they may lack a baccalaureate degree.

On balance we think clarity would be served and doubt removed by using the S. 705 language. In addition we think the alternatives provided by this language would give the Secretary even greater flexibility if changed to read "appropriate training, experience or examination requirements".

Related to the issue of personnel standards is the continuing problem of discrimination faced by the membership of AMT in hiring and job benefits practiced by federal, state and private hospitals, and independent labs which require a baccalaureate degree or which favor personnel certified by the American Society of Clinical Pathologists (ASCP). It is a problem not only for those lab personnel registered with AMT but also for laboratory personnel certified by other registries or not certified at all.

We brought this problem to the Subcommittee's attention in our testimony on S. 705 and also in our testimony on H.R. 6221 and the respective Senate and House reports did express disfavor with these discriminatory practices. However those bills did not become law. Meanwhile the discrimination continues and has in effect been endorsed by ASCP. This is made clear by our letters (copies attached) of February 16, 1979 and March 7, 1979 to Senator Jacob K. Javits and the staff of the Subcommittee describing in detail the discrimination problem. While it appeared to us that the discrimination problem could readily be eliminated by a specific provision in the bill, perhaps the Committee may consider this result would be achieved through condemning the practice in the Committee report by language directing the Secretary to assure that in prescribing personnel regulations pursuant to the Act no individual otherwise qualified for a particular laboratory rating shall be denied that rating solely because of his failure to meet professional membership requirements. The important thing is that the practice be eliminated and a clear statement by the Committee would be very helpful in that regard.

There is simply no evidence that laboratory technologists and technicians who possess a college degree or ASCP certification perform their tasks more competently than others. However there are studies which demonstrate that non-degreed technical personnel perform an overwhelming percentage of the same tasks performed by technologists certified ASCP, some possessing baccalaureate degrees some not, since ASCP has required a college degree for its certified technologists only since 1974. Entities requiring ASCP certification as a condition for employment for new personnel are in effect

requiring a college degree for technologist status which is contrary to the letter and spirit of S. 590. A further important adverse effect of such a degree requirement is to increase average laboratory personnel costs contrary to Administration and Congressional cost control goals.

We point out that the inclusion of an anti-discrimination provision in CLIA or a direction to the Secretary that personnel regulations promulgated by him reflect this anti-discriminatory policy would not represent the first time Congress and the Secretary have recognized the need for such measures. The 1972 amendments to the Social Security Act included a provision, 42 USC § 1320(a)-2(a), directing the Secretary of HEW to develop a program designed to determine the proficiency of individuals including laboratory technologists and cytotechnologists to perform the functions of their particular fields where those individuals did not meet formal educational, professional membership, or other established criteria. In developing such a program HEW was directed to employ procedures for the formal testing of the proficiency of individuals under the following specific requirements:

In the conduct of such program, no individual who otherwise meets the proficiency requirements for any health care specialty shall be denied a satisfactory proficiency rating solely because of his failure to meet formal educational or professional membership requirements.

All of this is said to ask and urge the Subcommittee's help in eliminating this indefensible discrimination against competent laboratory personnel not certified by ASCP. We think this effort would be consistent with the purposes of the legislation requiring the Secretary of HEW to prescribe personnel

qualifications which shall not be limited to educational requirements but which shall include as alternative requirements, appropriate training, experience or examination requirements. The goal of the bill that national standards "assure consistent performance by clinical laboratories of accurate and reliable laboratory tests" is not enhanced by denying employment to laboratory technicians and technologists who are qualified and proficient but who happen not to be certified by the American Society of Clinical Pathologists.

Another matter related to national standards for laboratory personnel concerns grandfathering of existing personnel. We urge that in developing national personnel standards the Secretary will include an appropriate grandfather clause which will recognize the fundamental fairness of protecting the rights of practitioners growing out of the pre-regulation practice of their laboratory occupations. In this connection the existing grandfather provisions as to technologists are badly out of date, providing that an applicant must be qualified as a laboratory technologist before July 1, 1961 and must have: (A) been performing the duties of a clinical laboratory technologist at any time between July 1, 1961, and January 1, 1968; and (B) has at least ten years of pertinent clinical laboratory experience or education prior to January 1, 1968. (20 CFR § 405.1315(b)(5)). These provisions should be updated to provide that an applicant will be covered by the grandfather clause if he is qualified as a laboratory technologist before the date of the enactment of this Act, has been performing the duties of a clinical laboratory technologist at any time between the date of enactment of the Act and three years previous and had at least five years of pertinent

clinical laboratory experience or education prior to the date of enactment of this Act.

In addition we know that some of the grandfather provisions promulgated previously by DHEW did not operate to grandfather qualified personnel. For instance individuals who were acting as technologist laboratory supervisors at the time of promulgation of the grandfather regulations and who subsequently qualified as technologists pursuant to the HEW proficiency examination, were nevertheless required by HEW regulations to satisfy an additional period of at least 6 years as technologists before they would be qualified as supervisors (20 CFR § 405.1313(b)(3)). In effect this means that there has been no grandfather clause at all with regard to supervisory technologists. This should not be repeated in connection with the regulations promulgated pursuant to CLIA 1979.

Some qualifications on grandfather provisions are certainly appropriate but the conditions adopted must not be so restrictive as to eliminate persons from continuing in the practice of their professions. The current shortage of laboratory personnel should also be kept in mind as well as the consequent upward pressure on lab costs which could be precipitated by a reduced personnel pool. In addition the skills of existing practitioners will be maintained pursuant to other provisions in the bill directed at assuring the continued competence of lab personnel.

With further regard to the national standards prescribing qualifications for laboratory personnel, we support and are pleased to see the two year grace period for rural labs provided in Section 372(f)(2). As that provision recognizes, rural labs have an especially difficult time in hiring individuals

with credentials that match those available to the urban laboratory job market. We agree that laboratory personnel competence and efficiency is no less needed in rural laboratories but that flexibility is required in meeting those goals.

Amendments to the bill by Senator Javits and approved by the Subcommittee authorizing the Secretary to exempt laboratory tests performed in physicians' offices in connection with the treatment of their patients and exempting state and local government owned and operated labs, pending the results of studies on the quality of services provided by such laboratories and an evaluation of the effect on quality of various quality assurance programs in such laboratories, appear to us to represent a reasonable approach. It should be recalled that AMT suggested in its testimony on S.705 utilization of a similar approach in connection with personnel standards for other labs covered by the bill in view of the study of such standards mandated by what is now Section 379 of the bill. The primary reason for the difference in the proposed regulatory treatment appears to be based in administrative difficulties pleaded by HEW. However, until sufficient statistics and data are available from both studies referred to there appears to be no immediate need for the different regulatory treatment. Further we fear continuing discriminatory treatment as discussed above by such laboratories against our membership if these categories of laboratories are exempted from national standards promulgated by the Secretary.

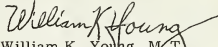
Finally we regret the elimination in S. 590 of a provision for creation of an Advisory Council to "advise, consult with, and make recommendations to, the Secretary" with respect to national standards and their implementation.



It should be noted that Section 372(d) provides that the Secretary, "in consultation with appropriate professional organizations," shall develop job-related proficiency and practical examinations, mechanisms designed to assure the continued competence of such personnel, and standards for the proficiency testing of laboratories. Secretarial consultation in this regard would seem to us to be greatly facilitated by the existence and ready availability of an Advisory Council.

We thank the Subcommittee for this opportunity to comment and invite questions on its content at anytime.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "William K. Young", written in a cursive style.

William K. Young, M.T.  
Washington Representative-AMT  
4880 - 66th Avenue  
Hyattsville, Maryland 20784



## COORDINATING COUNCIL FOR CLINICAL LABORATORY TECHNOLOGY

P.O. BOX 3723 WASHINGTON, D.C. 20017

February 9, 1979

The Honorable Joseph Califano, Jr.  
 Secretary  
 Department of Health, Education  
 and Welfare  
 Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the Coordinating Council for Clinical Laboratory Technology (CCCLT), we must share with you our deep concern about the course of events inside the Department which affects the drafting of proposed uniform laboratory personnel standards.

The Council is composed of three leading professional laboratory organizations: the American Society for Medical Technology (ASMT), the American Medical Technologists (AMT), and the International Society for Clinical Laboratory Technology (ISCLT). Combined, these member organizations represent nearly 50,000 nonphysician clinical laboratory personnel including administrators, supervisors, educators, technologists, technicians, and a variety of laboratory specialists.

It is our understanding that uniform laboratory personnel standards under development since 1975, were re-drafted recently and are scheduled to reach your desk in the next few weeks. On the basis of information available to the Council regarding the thrust of these draft regulations, we are surprised and concerned that you may be asked to consider and propose the elimination of important categories of personnel now covered by appropriate standards in certain laboratory settings. It is difficult to reconcile such a course of action given the position of the Public Health Service (PHS) with respect to the reliability of laboratory testing. In this regard, the PHS stated in its Forward Plan for Health, FY 1978-82 that "the accuracy and precision of laboratory results continue to be a national problem, with error rates ranging from 8-25 percent."

Moreover, the current "simplified" proposal in reality represents a clearcut dilution of standards and one which is far more drastic than any envisioned in a previous HCFA-PHS agreement on revised standards, an agreement subsequently disregarded on the advice of your General Counsel.

The Honorable Joseph Califano, Jr.  
February 9, 1979

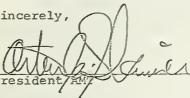
page 2


In the view of CCCLT member organizations the current course of actions runs counter to the real spirit of your "Operation Common Sense" initiative. Our organizations have been fully supportive of the goals of this initiative to make HEW regulations clear and less burdensome, and to eliminate those that are ineffective or outdated. Although some may interpret this to mean eliminating as many regulations as possible, we are confident that the Council and the Department agree that the critical challenge here is to assess and judge rules in the light of their bearing on vital public interests.

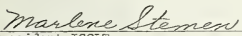
The development of uniform laboratory personnel standards clearly stands as a vital public interest. Since 1974 the Congress has shown continuing concern about the clinical laboratory field. In legislation which has passed the Senate twice it has signalled its clear intent that the Department develop appropriate personnel standards. Further, the experience gained over the last decade in HEW's interstate and Medicare laboratory programs underscores the need for such standards development. It is therefore of great concern to us that the Department may be preparing to reverse direction and recommend action that will not adequately protect or promote the public interest in the clinical laboratory field.

Under these circumstances, the Council is requesting a meeting with you and your designated staff. This meeting would enable us to discuss our serious reservations about the current course of proposed standards development prior to your final decision on this important issue.

Sincerely,

  
\_\_\_\_\_  
President/AMT

  
\_\_\_\_\_  
President ASMT

  
\_\_\_\_\_  
President ISCLT



## American Medical Technologists

February 16, 1979

Senator Jacob K. Javits  
Senate Committee on Human Resources  
Dirksen Senate Office Building  
Room 4233  
Washington, D.C. 20510

Attention: Mr. John Rother  
Senate Courts Building  
Room 401

Re: CLIA 1979, Discussion  
Draft No. 1, (1/25/79)

Dear Senator Javits:

This letter is written on behalf of the American Medical Technologists (AMT) and pursuant to our recent discussions with Mr. John Rother concerning CLIA 1979, Discussion Draft No. 1.

As you may recall from our previous testimony on S. 705, AMT was founded in 1939 and is the oldest, and with a membership of more than 12,000, the largest independent (that is not owned by physicians) registry of laboratory technicians and technologists in the U.S. It has long been interested in adequate laboratory personnel standards and is itself a standards setting organization both for personnel and for schools teaching laboratory personnel.

AMT is a registry, admission into (membership in) which is gained only after the applicant proves proper training and experience and passes an examination. AMT is the sponsor of the Accrediting Bureau of Medical Laboratory Schools (ABMLS), an autonomous agency, which has been certified by the U.S. Office of Education as a nationally recognized accrediting agency. The Bureau is the oldest technician-education accrediting agency and the first recognized by the Commissioner of Education in the field of laboratory technicians education.

Officers and staff of both AMT and of the Accrediting Bureau have consulted over the years with state and federal agencies, including the Department of Health, Education and Welfare, and the Social Security Administration concerning the required standards for laboratory personnel. We feel that we have contributed substantially to the field of public regulation of laboratories and we have ourselves benefited as a consequence of these exchanges of views and data with public officials.

Senator Jacob K. Javits  
February 16, 1979  
Page two

Our continuing concern with laboratory personnel standards as they affect the general public interest and welfare and with the effects of such legislation on the consonant and specific interests of our membership prompts the following comment on our part with regard to Discussion Draft No. 1.

As we stated in our testimony with regard to a similar provision in S. 705, we are pleased to see Section 372(b) which provides, *inter alia*, that the Secretary of HEW shall "...prescribe qualifications for supervisory personnel..., laboratory technical personnel, and any other laboratory personnel which qualifications shall (A) not be limited to education requirements but shall include as alternative requirements appropriate training, experience, and examination requirements, (B) include requirements designed to insure the continued competence of laboratory personnel..."

AMT has long supported the need for recognition of suitable experience and demonstrated competence by laboratory personnel rather than foreclosing such people from placement and upward progression on the basis that they lack a baccalaureate degree. It is AMT's policy of upward progression to require additional practical experience and examinations to qualify for advancement. In this regard we have always supported alternative avenues to qualification such as the DHEW proficiency examination, the administration of which has recently been extended by the Secretary.

However, we respectfully urge that § 372(b) discussed above concerning the Secretary's standard setting for laboratory personnel be amended prior to introduction to remedy long-standing and continuing discrimination by federal, state and private hospitals and independent labs against the membership of not only AMT but other qualified laboratory technologists not registered by the American Society of Clinical Pathologists (ASCP), a physician-owned registry.

To this end we suggest the following amendment to § 372(b)(4) to add a new subsection "(B)" and to redesignate existing subsections "(B)" and "(C)" respectively as "(C)" and "(D)" and also to add the words "except as provided in subsection B below" after the words "section 370(l)(A)" in lines 9-10 on page 8 of the Discussion Draft. This new subsection (B) would provide that the Secretary shall prescribe qualifications which shall:

(B) prohibit discrimination in the hiring compensation or the terms, conditions, or privileges of employment by any entity defined in §§ 370(l)(A), 370(l)(B) and 374 including laboratories described in subsections 374(a)(1) and (2) against any employee or job applicant, who otherwise meets the proficiency requirements for any health care specialty, solely because of his inability to meet formal educational or professional membership requirements.

Senator Jacob K. Javits  
February 16, 1979  
Page three

We believe that this amendatory language, when necessarily considered together with the bill's recognition that all labs are engaged in interstate commerce, § 2(3) and § 2(6), and the bill's enforcement provisions, §§ 371(c)(2)(A), 372(b)(5), 375(c), 375(f)(1), would require an end to these discriminatory practices which result in unemployment to non-ASCP certificants or in lesser salaries and benefits for the same work.

We point out that Congress previously recognized the need for non-discrimination in qualification standards for laboratory personnel when it passed 42 U.S.C. § 1320(a)-2(a) as one of the 1972 amendments to the Social Security Act. The section provided that the Secretary of HEW would develop a program, designed to determine the proficiency of individuals including laboratory technologists, and cytotechnologists to perform the duties and functions of their particular fields where such individuals did not meet formal educational, professional membership, or other established criteria. The statute provided that the HEW program would include (but not be limited to) the employment of procedures for the formal testing of the proficiency of individuals and most importantly states:

In the conduct of such program, no individual who otherwise meets the proficiency requirements for any health care specialty shall be denied a satisfactory proficiency rating solely because of his failure to meet formal educational or professional membership requirements.

Our earlier testimony on S. 705 discussed this problem of discrimination by laboratories in their hiring, promotion and salary practices and urged that no regulations be they federal, state or local be permitted to discriminate by requiring that laboratory personnel be of a particular registry to the exclusion of persons of a different registry, or no registry at all, but nevertheless having the requisite training and experience to perform the job competently.

Although S. 705 contains no language to such an end, the language of S. Rep. No. 95-360 accompanying S. 705 recognized the problem in its discussion of an alternative avenue to qualification, the DHEW proficiency examination, and expressed the committee's concern that:

Heretofore, the committee is concerned that these other governmental agencies and private hospitals have only recognized persons certified by the major credentialing body of the ASCP and have not recognized other credentialing agencies or proficiency examinations as equivalent to e.g., the MT-ASCP.

S. Rep. No. 95-360, 95th Cong., 1st Sess. 26 (1977).

Similarly the House bill, H.R. 10909, did not contain specific language aimed at remedying the discrimination problem but the House Report, H. Rep.

Senator Jacob K. Javits  
February 16, 1979  
Page four

No. 95-1004, Part I, 95th Cong., 2d Sess. 16 (1978), accompanying the legislation recognized the problem in terms of limiting qualification as technologists to "only persons with rigid academic credentials." Since 1974 ASCP has required all technologists certified by it to possess a B.S. degree and this requirement is in turn imposed by federal, state and private hospitals and independent labs when they refuse to hire anyone without an ASCP certification. AMT certified technologists have even been refused employment when they possess a baccalaureate degree but no ASCP certification.

We are appreciative of the Congressional recognition reflected in the House and Senate Reports but believe that specific language is required in the bill to eliminate this continuing injustice to qualified technologists not registered with ASCP. It is clear that discriminatory practices are continuing in federal agencies, state and private hospitals and independent labs. For instance, as the Senate Report discussed above makes clear, the Civil Service Commission, DOD and VA labs will often not even recognize the DHEW proficiency exam. In addition these agencies often continue to discriminate in favor of ASCP registered personnel to the detriment of all others not possessing that affiliation.

This is also the practice of several states having licensure laws which do not recognize the DHEW proficiency examination or non-ASCP certifications as valid alternative avenues for qualification as a technologist.

The discriminatory practice is indeed widespread, and it continues with full awareness of its existence and effects. For instance an article appeared in the July 1978 issue of the "ASCP Newsletter" in which ASCP's legal counsel expressed the following:

It is our opinion that there are no provisions of federal law which prohibit a pathologist or other prospective employer in an employment advertisement from specifying the credentials of medical laboratory personnel based solely upon ASCP certification, without including the qualifier of equivalent credentials. We have not examined the laws of the various states, but we are aware of none which would differ significantly from federal law in this respect.

The deleterious effects upon non-ASCP registrants resulting from such a view should be obvious. Although we cannot agree with the legal conclusion expressed, the outcome of a current legal challenge to such discriminatory practices is uncertain at best. AMT spends considerable time and resources on an ad hoc basis attempting to remedy these practices in response to numerous pleas for help from our membership; we are sometimes successful, sometimes not.

Senator Jacob K. Javits  
February 16, 1979  
Page five

However specific language in CLIA 1979 could bring these practices to an end. Such language is needed and is consistent with the goals and language of the current Discussion Draft providing that personnel qualifications set by the Secretary shall "(A) not be limited to education requirements but shall include as alternative requirements, appropriate training, experience, and examination requirements." It does not serve to "insure the accuracy and reliability of performance of tests" by clinical laboratories to deny employment to those technologists which have shown themselves to be otherwise qualified "but for" the initials ASCP. Furthermore Section 372(b)(4)(B) assures competent personnel performance by requiring that the Secretary "include requirements designed to insure the continued competence of laboratory personnel." There is thus no legitimate reason for any lab to require its technologists or technicians to be affiliated with a particular registry. In addition it should be stated that there is no evidence that those technologists possessing a B.S. degree or more specifically those technologists certified by ASCP (many not possessing a B.S. degree) perform more competently than others.

There are tests and surveys however that indicate that in most labs 95% of the tasks performed by technologists are performed by technicians.\*/ In fact one of these studies \*\*/ indicates that those laboratory employees certified CLA-ASCP perform 95% of the tasks performed by those employees certified MT-ASCP. The requirements for certification as a CLA-ASCP are approximately 100 hours of classroom education and 48 weeks of training; for an MLT-ASCP, an A.A. degree plus six months training; for an MT-ASCP a B.S. degree plus one year of training or completion of a program including three years classroom and one year's training leading to a B.S. degree. These standards should be compared with those for certification by AMT: MLT-AMT requires at least 1,500 clock hours of classroom education and one year's training; MT-AMT requires that the individual possess the requirements necessary for certification as an MLT-AMT plus three years training or ninety semester hours plus one year's training, or a B.S. degree plus one year's training.

Comparison of these standards together with the results of the studies referred to above again makes abundantly clear the discriminatory and unnecessary nature of the "ASCP only" requirement.

If CLAs-ASCP, possessing far less education and experience than either

\*/ See for instance: "Job Analysis in the Clinical Laboratory," American Journal of Medical Technology, Volume 42, Number 5, May 1976; "Job Restructuring for the Clinical Laboratory," Kettering Medical Center, Revised March 1976, NIH Special Projects Grant No. A11 00249 U.S. Department of Health, Education and Welfare; "Cancer Entry Job Descriptions for MT/MLT," Kettering Medical Center, May 1977, NIH Special Projects Grant No. A11 00249, U.S. Department of Health, Education and Welfare.

\*\*/ "Job Analysis in the Clinical Laboratory," supra.



Senator Jacob K. Javits  
 February 16, 1979  
 Page six

technologists or technicians certified by AMT, are performing 95% of the tasks performed by MTs-ASCP there is no justification for refusing to hire an AMT-certificant to perform such tasks. Furthermore with regard to the 5% of tasks performed by technologists but not technicians or CLAs, there is no evidence that MTs-ASCP perform these tasks more competently than MTs-AMT.

The MT-ASCP requirement results in laboratories being unnecessarily overstaffed with degreed personnel thereby putting upward pressure on costs which is of course a very current concern of Congress and the Administration. In addition, it should be noted that although DHEW currently has underway a study to evaluate the relationship between scores on the DHEW proficiency exam and actual lab performance, DHEW has expressed its satisfaction with the performance to date of those qualifying pursuant to the alternative avenue of qualification offered by the DHEW proficiency exam.

AMT's files are filled with letters from our membership, which we would be glad to make available to you or the Committee staff upon request, setting forth their personal cases of suffered discrimination and pleading for our help. CLIA provides the prospect of a solution to their problem.

While AMT supported S. 705, the inclusion of an anti-discriminatory provision, such as described above, in CLIA 1979 would give the AMT membership an additional and very real reason to rally round this legislation. We therefore ask your consideration of the amendatory language we have suggested and stand ready to answer any questions you or your staff may have concerning this matter.

Our reading of the Discussion Drafts indicates no substantial changes in those provisions about which we testified in connection with S. 705, and we have therefor not commented further at this time concerning such provisions.

However, we do point out a current development in the laboratory regulation area which is of substantial concern to us. The preliminary indications are that the Secretary of HEW is considering the elimination of qualification standards for laboratory technicians and technologists which we believe runs fully counter to the objective of the proposed CLIA legislation providing that the public interest and health and welfare of consumers of health care requires that "all clinical laboratories comply with uniform standards to assure accurate and reliable testing...". It is our opinion that in order for that objective to be achieved it is absolutely essential that adequate standards for laboratory technicians and technologists be developed. This need is further emphasized by the studies referred to above which indicate that 95% of laboratory tests are performed by technician personnel.

Senator Jacob K. Javits  
February 16, 1979  
Page seven

We thank you for this opportunity to comment and appreciate your consideration of our views.

Respectfully submitted,

William K. Young, MT  
Washington Representative for AMT  
4880 66th Avenue  
Hyattsville, Md. 20784



## American Medical Technologists

March 7, 1979

Honorable Jacob K. Javits  
Russell Senate Office Building  
Room 321  
Washington, D.C. 20510

Dear Senator Javits:

In an earlier letter dated February 16, 1979, AMT took the opportunity to comment on CLIA 1979 (Discussion Draft No. 1) received from Mr. Rother. That letter principally addressed AMT's view of the need for an anti-discrimination provision in CLIA which would prevent discrimination by federal, state and private hospitals and independent labs on the sole basis of registry affiliation.

Because we understand that CLIA may soon be introduced without such a provision we wish to reaffirm our view of the need for such a section in the CLIA bill. We think specific statutory language aimed at eliminating the discrimination problem is needed and is consistent with our understanding that the proposed legislation will require the Secretary of HEW to prescribe personnel qualifications which shall not be limited to education requirements but shall include as alternative requirements, appropriate training, experience and examination requirements. The goal of the bill that national standards "assure consistent performance by clinical laboratories of accurate and reliable laboratory tests" is not enhanced by denying employment to laboratory technicians and technologists who are qualified and proficient but who happen not to be certified by the American Society of Clinical Pathologists. As we pointed out in our earlier letter, there is no evidence that those laboratory technologists and technicians who possess a college degree or ASCP certification perform their tasks more competently than others but there are studies which demonstrate that non-degreed technical personnel perform an overwhelming percentage of the same tasks performed by technologists certified by ASCP, some possessing college degrees, some not, since ASCP has required a college degree for its certified technologists since only 1974. Entities requiring ASCP certification as a condition of employment for new personnel are in effect now requiring a college degree for technologist status which would be totally contrary to the letter and spirit of the bill. A further important adverse effect of such a degree requirement is to increase average laboratory personnel costs which is contrary to current cost control goals of the Administration and Congress.

As we have indicated, the inclusion of such an anti-discrimination provision in CLIA would not be the first time Congress has recognized the

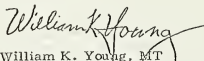
Honorable Jacob K. Javits  
 March 7, 1979  
 Page two

need for such a provision. One of the 1972 amendments to the Social Security Act, 42 USC §1320(a)-2(a), directed that the Secretary of HEW develop a program designed to determine the proficiency of individuals including laboratory technologists and cytotechnologists to perform the functions of their particular fields where those individuals did not meet formal educational, professional membership, or other established criteria. In developing such a program HEW was directed to employ procedures for the formal testing of the proficiency of individuals under this specific requirement:

In the conduct of such program, no individual who otherwise meets the proficiency requirements for any health care specialty shall be denied a satisfactory proficiency rating solely because of his failure to meet formal educational or professional membership requirements.

We urge the same approach as part of the CLIA legislation. Such an approach would not only be consistent with the goals of the legislation but would also be of great individual personal benefit to all qualified technicians and qualified technologists not certified by ASCP. Such a provision would bring an end to the unfair and continuing discrimination by federal, state and private hospitals and independent labs against such qualified people. We can conceive of no justifiable opposition to the elimination of such a discriminatory practice. We therefore urge inclusion of such a section in CLIA and thank you for your consideration.

Sincerely,



William K. Young, MT  
 Washington Representative - AMT  
 4880 66th Avenue  
 Hyattsville, Md. 20784

cc: Mr. John Rother  
 Senate Committee on Human Resources  
 Subcommittee on Health and Scientific Research  
 Dirksen Senate Office Building  
 Room 4230  
 Washington, 20510

STATEMENT  
of the  
AMERICAN MEDICAL ASSOCIATION  
to the  
Committee on Labor and Human Resources

Re: S. 590, The Clinical Laboratory  
Improvement Act of 1979

April 10, 1979

The American Medical Association submits the following statement relating to S. 590, The Clinical Laboratory Improvement Act of 1979, for consideration by the Committee on Labor and Human Resources.

The federal government has been actively involved in the regulation of certain clinical laboratories since the enactment of the original Clinical Laboratories Improvement Act of 1967. Regulation under this Act has been limited to laboratories involved in interstate commerce, with States retaining a major role in their regulation. In recent years, however, Congress has explored ways to expand the scope of federal activities, both in terms of the numbers of laboratories to be regulated and in terms of the extent of federal standardization of operational requirements. The principal expansion would be to laboratories involved only in intrastate commerce, including those in physicians' offices.

S. 590 would subject all clinical laboratories, including those in physicians' offices, to an extensive system of federal regulation that would cover laboratory quality control, personnel, proficiency-testing and licensure.

Certain limited exemptions from coverage would be provided for physicians' office laboratories, certain laboratories in rural areas, and laboratories engaged in research activities.

#### Comments

##### Definition of Clinical Laboratory

To understand more completely the far-ranging effects of the proposed inclusion of intrastate laboratories, we must first look to the proposed definition of "laboratory."

The present definition provides that--

The term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man.

This definition clearly contemplates coverage of only those facilities which examine specimens in order to diagnose, prevent, or assess any disease in man.

However, S. 590 would expand current law by adding to the present definition:

or a facility for the collection, processing and transmission of such materials for such purposes, other than a facility exclusively engaged in the collection or processing of human blood or its components intended for transfusion or further manufacturing.

This broadened definition could include under federal regulation VD clinics, genetic counseling clinics, TB clinics, family planning clinics, neighborhood

health centers, and any other facility which itself may not analyze human material but which may provide services for the "collection, processing and transmission" of human material for analysis by a laboratory. This definition would also include a physician's office, irrespective of whether he even has a "laboratory" for diagnostic tests or examinations.

We believe that the implications of this amended definition are so far-reaching that it should not be adopted. We do not believe that collection facilities should be deemed clinical laboratories, and as such subject to the provisions of the bill.

The definition used in the present law should be retained.

#### Exemption for Physicians' Laboratories

S. 590 would allow certain limited exemptions from the national standards and thus from licensure. For example, for a period of time national standards would not apply to clinical laboratories not in interstate commerce or to certain clinical laboratories located within and serving rural areas. The Secretary would also have authority to grant exemptions to laboratories in certain physicians' offices and for laboratories engaged in biomedical or behavioral research.

Present federal law expressly exempts from regulation the laboratory of a physician when used solely as an adjunct to treatment of his patients. This present exclusion should be maintained. The imposition of a new program of federal regulation of the physician's laboratory, an integral aspect of medical practice, is unnecessary. There are many factors currently assuring proper practice by physicians in their own office laboratories.

Under the provisions of S. 590, a physician's laboratory could be exempt only under certain very limiting conditions.

The Secretary could by regulation exempt from the national standards any clinical laboratory (a) which is located in the office of, and operated by, a licensed physician,

dentist or podiatrist, or a group of not more than five such practitioners, and (b) in which the only tests or procedures performed are routine tests or procedures (as determined by the Secretary) performed by the practitioner in connection with the treatment of his patients.

A further provision is made, with respect to groups of up to five physicians, as above, that the national standards may not apply if the clinical laboratory successfully participated in a proficiency-testing program approved by the Secretary, and the program operator agreed to provide information to the Secretary respecting the results of the proficiency tests administered under such program.

Under the highly tentative nature of "exemptions" for the physician's office, it is not clear to what extent the Secretary "may" exempt any such laboratory. It is not even clear whether the proficiency-testing program exemption would be applicable to all laboratories. Furthermore, by conditioning the exemption provisions "upon such conditions as the Secretary may by regulations prescribe," it is easy to envision "standards" as complex and detailed as are the standards which would otherwise apply to all other laboratories ostensibly covered by the bill.

The requirement (for physician office laboratory exemption from national standards) that only routine tests or procedures be performed, and that all such tests or procedures be performed by the physician, is unrealistic and too restrictive.

As we have pointed out above, any provision that does not clearly specify that the physicians' office laboratories are not subject to national standards is inappropriate and should be stricken.

There are additional, more general, considerations militating against the application of the national standards to physicians' office laboratories.

Applying the new national standards (or others equally strict) to the laboratory of the treating physician could discourage the performance of services now



customarily done in the physician's office, thus necessitating an additional visit by the patient to an outside laboratory for laboratory service. Since such laboratories may not be readily available, the inconvenience would be especially onerous to patients who may have to travel long distances or at additional expense or time for access to laboratory services.

There is an even more fundamental objection to the bill's application to the physician's office. We must protest strongly any proposal to vest in the federal government control of an integral part of the physician's practice. There is no evidence of danger or risk to patients sufficient to justify the regulation of the physician's office laboratory.

The exemption for physicians' office laboratories contained in the present law should be retained.

#### Employee Provisions

The bill would prohibit discrimination against, or firing of, laboratory personnel who participate in any investigation or prosecution of any violation of law by the laboratory employer. While the objective may be laudable, we are concerned that such provisions are an invitation for reverse intimidation, and could produce unfavorable effects.

#### Role for Professional Associations

Provision is made in the bill to allow for laboratory inspections and for proficiency-testing of laboratories and their personnel by private non-profit organizations having standards as stringent as the national requirements. We believe that this provision should be supported. If organizations currently

performing equivalency accreditation would be the examining agencies under the bill, we believe that they would provide the advantages of past experience along with a greater opportunity for innovation. Moreover, we would see merit in a fuller accrediting role for these private bodies.

#### State Role

State agencies under agreement with the Secretary to determine compliance by clinical laboratories with the conditions of participation under Medicare would also be utilized for the purpose of determining whether clinical laboratories in their States meet the requirements of licensure. We believe that the States have primary jurisdiction over intrastate laboratories and we would urge that any national program encourage such State participation. While we question the desirability of establishing uniform national standards, as contemplated in S. 590, we believe that emphasis should be given to State programs in any national legislation.

#### Changes in Medicare

In addition to proposing changes in the present laws to bring virtually all clinical laboratories under federal regulation, S. 590 would effect broad changes in the Medicare laws. New provisions would require special detail on physicians' billings that include charges to a patient for a laboratory test. The detail would include identification of a laboratory that performed such a test and indicate the amount charged to the physician who submitted the bill; it would also limit the physician's fee to the laboratory charge plus a nominal handling fee. Moreover, these provisions would require, as a condition for payment for a laboratory service performed in the physician's office, that the physician certify on

the bill that he personally performed or supervised the performance of the test. We believe that this is an unnecessary imposition on the physician, and this requirement should be eliminated.

The menacing encroachment of government in the practice of medicine comes into sharper focus when we examine other provisions in the bill that would change the definition of "physicians' services" in the Medicare law. We would like to call the attention of the Committee to the far-reaching implications of this change and other Medicare changes incorporated in S. 590.

#### Hospital-Associated Physicians

S. 590 would establish a stringent definition of "physicians' services," and would enact statutory definitions of reimbursable pathology services. This section would also reduce the Medicare payment for radiology and pathology services if the physician providing them did not accept assignment; and would limit physician reimbursement based upon the form of financial arrangements. These provisions are highly objectionable.

Medicare law now defines "physicians' services" as professional services performed by physicians. S. 590 would amend that definition to exclude the services the physician performs as an educator, an executive, or a researcher. The amendment would exclude even patient services unless "personally performed by or directed by a physician" for the benefit of the patient and unless the service is of such a nature that its performance "by a physician is appropriate."

It should be made clear that although this redefinition of physicians' services comes under the heading "hospital-associated physicians," it is not so limited, and the placement of the amendment under that heading is misleading. In

fact, the provision amends the general definition of "physicians' services" in Section 1861(q) of the Medicare law and consequently the new limitations apply to all physicians' services under Medicare.

We object strongly to these modifications. All activities of physicians customarily recognized as part of the physician's practice should be reimbursable as "physicians' services" under Medicare. A strict application of the proposed language would have dire consequences for proper recognition of, and payment for, all services of physicians under Medicare.

Even if the provision was intended to affect only the inpatient services of "hospital-associated physicians," the modification would be very objectionable. The writers of regulations, armed with this proposed statutory language, could arbitrarily redefine the practice of medicine as recognized today to the detriment of both the patient and the profession.

Whatever its intent, a legal definition that states that a physician acts as a physician only when directly treating a patient and when performing services only a physician can perform will ultimately lead to confusion in the Medicare program and further dismemberment of health care.

Furthermore, the physician as educator, researcher, or administrator does not cease to be a physician; indeed, since the earliest days of the medical profession, teaching and research have been recognized as intrinsic parts of the practice of medicine. As medicine has become more organized and technologically sophisticated, administrative tasks have developed which can be performed most effectively by a practicing physician.

We protest strongly any artificial division of the physician's role.

The bill would say which services of pathologists are "physicians' services" and which are not. This attempt to redefine pathology services for purposes of Medicare and Medicaid reimbursement can only have an adverse affect on the availability of pathology for the patients under those programs.

S. 590 would modify Medicare reimbursement to "encourage" physician acceptance of assignments, and it would do so by penalizing the patient if they do not. Under present law, pathology and radiology services are paid under Part B at 100% of the "reasonable charge," whether the physician has accepted assignment or not. The proposed amendment would change the amount of Medicare payment to the usual 80% of the "reasonable charge" if the physician does not accept assignments and permit crediting of the patient's 20% of the "reasonable charge" towards the annual Part B deductible. We point out that the "reasonable charge" for pathology and radiology services remains the same, whether or not the physician accepts assignment.

During the discussions prior to the passage of P.L. 90-248, we questioned whether the coinsurance factor should be eliminated for specific segments of medical care. We question even more strongly the establishment of different rates of payment by Medicare for similar services when provided on assignment or billed to the patient. We believe that this approach violates basic principles of equity to the Medicare beneficiaries, who pay the same out-of-pocket premium but would receive different degrees of coverage as a result of factors over which they have no control.

Finally, we oppose the provision that would alter reimbursement of physicians on the basis of the form of their financial arrangements with the hospital. The bill provides that the charges of a physician or other person related to income or receipts of a hospital or hospital subdivision

would not be taken into consideration to the extent that such a charge exceeded what a salary (plus certain expenses), as determined by the Secretary, would reasonably have been if the physician or other person had been employed by the hospital. We believe that freedom of contract should not be so limited.

The proposed redefinitions of "physicians services" are described as an effort to control health care costs by limiting reimbursable services under Medicare. In actuality, it is an effort by government to evade its responsibilities to Medicare beneficiaries who depend on this program for their health care. Changing the definitions does not change the true costs of services, but merely shifts the burden of financial responsibility from the government to the patient who can ill-afford such a shift.

We strongly urge that these changes not be adopted.

#### Conclusion

To spell out briefly some of our major concerns with the proposed expansion of the federal authority to regulate clinical laboratories, we would point again to the following items.

First is the broadened definition of the term "laboratory" that could lead to federal regulation of physicians' offices that do not have laboratories, but that do collect, process and transmit samples of human material for later laboratory procedures.

Second is the subjugation of all physicians' office laboratories to national standards and federal licensure. As we have pointed out, the opportunities for exemption of the physician laboratory are severely restricted and could be meaningless in practice.

We believe that the physicians' offices should not be brought under

federal licensure and regulation, and that the present definition of "laboratory" should be retained.

We are deeply concerned also with the effort through S. 590 to re-define "physicians' services" and enable government personnel to preempt medical judgements in the determination of what is a professional service under the Medicare laws. We object strongly to the inclusion of this and the other board changes that would impact severely on the entire Medicare program.

We urge the Committee not to adopt S. 590 as the bill is presently written.

## AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS

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815 SIXTEENTH STREET, N.W.  
 WASHINGTON, D.C. 20006

(202) 637-8000

April 10, 1979

Honorable Edward M. Kennedy, Chairman  
 Subcommittee on Health and Scientific  
 Research  
 Senate Labor and Human Resources Committee  
 United States Senate  
 Washington, D. C. 20510

Dear Mr. Chairman:

We would like to request that the enclosed statement on the  
 Clinical Laboratory Improvement Act of 1979 be included in the  
 record of hearings.

Sincerely yours,

*Kenneth Young*  
 Kenneth Young, Director  
 DEPARTMENT OF LEGISLATION



STATEMENT OF KENNETH YOUNG, DIRECTOR, DEPARTMENT OF LEGISLATION  
AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS  
SUBMITTED TO  
THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
SENATE COMMITTEE ON HUMAN RESOURCES  
ON THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1979  
S. 590

April 11, 1979

The AFL-CIO welcomes the opportunity of submitting its views with respect to the Clinical Laboratory Improvement Act of 1979 (S. 590) introduced by Senator Javits (R-N.Y.) with six cosponsors.

Senator Javits was largely responsible for the enactment in 1967 of a similar bill but which covered only about 750 laboratories doing interstate business. There are, however, about 15,000 clinical laboratories in the United States, about one-half of which are in hospitals. There are about 6,500 independent labs. Lastly, there are an unknown number but doubtless thousands of small laboratories run by private physicians in their own offices.

Except for the 750 labs in interstate commerce, therefore, the great bulk of clinical laboratories are unregulated.

Senator Javits indicated in 1967 that he hoped the states would enact similar legislation to cover laboratories doing an intrastate business but in the eight years that have transpired since then, only a very few states have acted.

Numerous studies have indicated that about 25 percent of all tests performed by laboratories yield erroneous results. It is known many labs do accurate work so that the 25 percent figure, which is an average, means that many laboratories have a poorer record. It is documented that some labs have an error rate as high as 50 percent.

Page 2

While medicine is not an exact science, medical advances have greatly improved the ability of physicians to make an accurate diagnosis and to institute appropriate therapy. The ability to make an accurate diagnosis depends to a high degree upon accurate and reliable diagnostic tests. No one really knows how many patients have died because of a faulty diagnosis followed by inappropriate treatment induced by inaccurate lab work. No one knows how many patients have been treated for a condition they did not have because of false reports from laboratories. No one knows the cost of inappropriate and/or unnecessary treatment caused by atrocious performance. No one knows how many malpractice suits have been initiated by patients against their doctors because of false laboratory results. Clearly, corrective measures are indicated.

Unfortunately, shoddy work, inadequate and even contaminated equipment, poorly trained personnel and careless management are only part of the problem. Laboratory testing is a \$12 billion-a-year industry and is usually used as a money maker by hospitals. Many independent laboratories are doctor-owned. Since it is the doctor who sends his specimens to the laboratory, the inherent conflict of interest in many instances is obvious.

The AFL-CIO has no objection to doctors investing in clinical laboratories as long as there is honest competition in the industry. However, it is the physician who chooses the laboratory in which his blood, urine or other samples are to be analyzed. Too many doctors give their lab work, not to the lowest bidder, but to the laboratory in which they are owners or stockholders. No wonder then that a doctor sends his specimens to a

Page 3

lab that charges \$45 for a test that could be done for \$10 in another laboratory. This is no less than a "rip-off" of the Medicare and Medicaid programs and of the patient.

Yet, when the New York City Health Department proposed to cut Medicaid lab costs by instituting a bidding system which the Department stated would save almost one-half of the city's \$11 million in annual lab payments, the independent laboratories were joined by the Department of Health, Education and Welfare in a friend-of-the-court brief that asserted that the city's proposal would violate the patient's freedom to choose providers of service.

Therefore, the AFL-CIO strongly recommends that a section be added to the bill which would require competitive bidding for all outside clinical laboratory work performed on behalf of patients covered by any federally financed health program.

The series of articles which appeared in the Newark Star-Ledger about the poor laboratory conditions in New Jersey and which were printed in the Congressional Record the day Senator Javits introduced his earlier bill in 1975 should cause concern about delegating licensing and regulating authority to the states. New Jersey is one of the few states which have enacted legislation to license clinical laboratories. To quote from the first article:

"The best regulated lab facilities in Jersey are the handful engaging in interstate trade. These facilities must meet the rigid standards of the federal government's Center for Disease Control (CDC) headquartered in Atlanta, Georgia. The standards include unannounced on-site inspections (which sometimes last two days), a comprehensive proficiency testing program, maintenance of safety codes and licensing of personnel."

Page 4

In spite of this, the AFL-CIO accepts Section 373(b) which authorizes the Secretary to utilize a state or local agency for the purpose of determining whether clinical laboratories in such state meet the requirements for a license under the bill.

The AFL-CIO also endorses the employee protection provisions of Section 375(d), which would give an employee recourse against an employer who discharged him for reporting violations of the law or for cooperating with enforcement officers.

While S. 590 is a weaker bill than what was originally introduced in 1975 by Senator Javits, it nevertheless represents a forward step. The AFL-CIO, therefore, urges S. 590 be reported out of committee with the changes we have suggested. We hope it will be passed by the Senate without any further weakening amendments.

STATEMENT  
OF THE  
AMERICAN CLINICAL LABORATORY ASSOCIATION  
on S. 590

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH  
OF THE  
COMMITTEE ON HUMAN RESOURCES AND LABOR

UNITED STATES SENATE

THE CLINICAL LABORATORIES IMPROVEMENT ACT OF 1979

WASHINGTON, D.C.

MARCH 1979

TESTIMONY OF THE AMERICAN CLINICAL LABORATORY  
ASSOCIATION ON S. 590, THE CLINICAL LABORATORY IMPROVEMENT  
ACT OF 1979

The American Clinical Laboratory Association (ACLA) submits this statement in support of S. 590, the Clinical Laboratory Improvement Act of 1979. Our support for legislation such as this was strong in 1975 when Senator Javits first introduced a comparable bill; our support remains as firm today.

ACLA is an association of large and small independent clinical laboratories that provide services to patients in every state in the country. Each ACLA member is licensed by the Center for Disease Control for interstate business or accredited for reimbursement pursuant to the Medicare Conditions for Coverage of Services of Independent Laboratories. Certification by either of these federal programs is a prerequisite to membership in ACLA because ACLA seeks to be a voice for the provision of high quality laboratory testing services and these two federal programs embrace those elements that are necessary to insure the reliability of laboratory testing. As a result of their participation in these two programs, ACLA members are known to be among the highest quality laboratories in the country.

Prompt enactment of this legislation is mandatory. In testifying on CLIA '76 and CLIA '78 before this Subcommittee and your sister Subcommittee on Health and the Environment in the House of Representatives, ACLA stressed the need for comprehensive

laboratory legislation to protect the American public from inadequate laboratory testing. Nearly four years have passed since Senator Javits and Senator Kennedy introduced S. 1737, the first of the laboratory bills of the 70's, and the need is as pressing now for enactment as it was then. ACLA commends this subcommittee for its prompt attention to this issue and its obvious commitment to improving clinical laboratory performance. Enactment is even more necessary today than it was two years ago because the volume of testing is growing rapidly and physicians are relying upon testing data with increasing frequency.

There is little we can add to our comments on S. 1737 and S. 705; we therefore request that you consider them to be a preamble to this testimony.<sup>1/</sup> However, an analysis of the current regulatory approach to laboratory performance clearly demonstrates why, despite the passage of four years, enactment of this legislation is still necessary.

Perhaps one of the best and most concise statements analyzing the problems plaguing the provision of testing services is found in the Department of Health, Education and Welfare's

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<sup>1/</sup> HEARINGS before the SUBCOMMITTEE ON HEALTH of the COMMITTEE ON LABOR AND PUBLIC WELFARE, UNITED STATES SENATE, on S. 1737, 94th Cong., 1st Sess., pgs. 214-220, 247-252, 855-867; HEARINGS before the SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH of the COMMITTEE ON HUMAN RESOURCES, UNITED STATES SENATE, on S. 705, 95th Cong., 1st Sess., pgs. 225-301.

recent Forward Plan for Health - F.Y. 1978-1982,<sup>2/</sup> (hereinafter "Forward Plan"). The Forward Plan acknowledges that laboratory error is a significant problem that has substantial economic and health consequences because physicians are relying increasingly upon "laboratory results to detect abnormalities, to modify or confirm a diagnosis, and to monitor the progress of therapy."<sup>3/</sup> According to HEW these errors stem principally from "inadequately trained and incompetent staff members; overworked or incompetent supervisors; use of inadequate or inappropriate procedures; failure to use controls regularly to verify the acceptability of test results; and errors in interpreting or transcribing test results."<sup>4/</sup>

ACLA believes that where laboratories are not subject to rigorous quality assurance programs, laboratory error will occur too frequently because incompetent personnel are employed, inadequate quality control is practiced and improper procedures are utilized. ACLA members, who have long been subject to intensive quality assurance regulation, know through experience that regulation can end these deficiencies. However, to date, a comprehensive uniform approach

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<sup>2/</sup> Forward Plan for Health - F.Y. 1978-1982, U.S. Department of Health, Education and Welfare, Public Health Service, Stock No. 017-000-00172-8 (August 1976), pgs. 66-67.

<sup>3/</sup> Ibid, p. 66.

<sup>4/</sup> Ibid, p. 67.



to regulating laboratories has not been adopted, even by the federal government.

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Regulation of Hospital Laboratories is Currently Inadequate  
and Should be Strengthened

Hospital laboratories continue to be inadequately regulated as the federal government still maintains less stringent standards for personnel employed in Medicare hospital laboratories than apply to personnel employed in interstate licensed or Medicare certified laboratories. The regulations applicable to interstate licensed and Medicare certified independent laboratories establish comprehensive specific experience, education and training prerequisites for directors, general supervisors, technical supervisors, medical technologists, cytotechnologists, technicians and technician trainees. 20 C.F.R. §§405.1312 - 405.1315. These regulations occupy six pages of the Code of Federal Regulations. The personnel standards for Medicare hospital laboratories are general and vague, comprising only one-half page of the Code of Federal Regulations. 20 C.F.R. §405.1028(d) and (g). These regulations, which are clearly inadequate, merely require physician or doctoral supervision of testing, an adequate number of qualified technologists and access to consultation with a pathologist.

ACLA believes that the differences in these personnel regulations illustrate that enactment of S. 590 is necessary to gain a consistent, uniform federal laboratory program. It is

interesting to note that the factors which HEW identifies in the Forward Plan as being the principal causes of laboratory error are all addressed in the comprehensive interstate and Medicare independent laboratory programs; many of them are ignored by the Medicare hospital regulations.

#### Too Few States Have Established Comprehensive Laboratory Programs

If all the states had established comprehensive laboratory quality assurance programs, as Senator Javits and other leading proponents of CLIA '67 hoped would occur, CLIA '79 would not be necessary. Unfortunately, many states have not, and overall state laboratory regulation is inadequate. Many states have no mandatory laboratory program. Many others only have programs that cover independent laboratories. Only a few have established comprehensive programs applicable to hospital and independent laboratories alike. The Forward Plan recognizes the problems caused by the varying state involvement in laboratory improvement, noting:

Compounding these problems [that cause laboratory error] has been the lack of an effective and coherent regulatory framework for assuring the quality of laboratory practice and performance. Before 1960, only three or four States had laboratory licensing laws other than for syphilis serology. Even today, only 16 States have effective licensure laws, and no two of these are alike. The Clinical Laboratories Improvement Act (CLIA), enacted in 1967, was intended to regulate clinical laboratories doing business in interstate commerce, with the Federal government exercising its regulatory authority to support

the integrity of and serve as a model for State improvement programs. However, since only laboratories in interstate commerce are required to meet established standards, intrastate laboratories have been able to operate in States with less stringent standards, thereby undermining strong improvement programs in other States. 5/

A federal mandate is therefore necessary to assure that all laboratories not presently so subject become subject to uniform comprehensive quality assurance standards governing personnel qualifications, internal quality control, successful participation in proficiency testing programs and proper maintenance of records, equipment and facilities. S. 590 would accomplish such mandate for independent and hospital laboratories.

Physicians' Office Laboratories Should Be Subject to Federal Standards

While S. 590 would direct the Secretary to regulate independent and hospital laboratories, it would authorize the Secretary of HEW to exempt qualifying physicians' office or group practice laboratories of five or fewer. ACLA believes that all laboratories should be subject to the federal standards, as a minimum, to assure the accuracy and precision of all testing services. Thus, ACLA urges that the exemption authority be deleted from the bill. Every patient is entitled to expect accurate testing results regardless of the type of laboratory performing the testing.

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5/ Ibid, p. 67.

The Need for Uniform Standards

ACLA believes that the most effective way to assure quality performance is to establish a regulatory system based on a single set of uniform standards promulgated by the Secretary. Until such time as uniform standards applicable to all laboratories are developed, performance will vary. ACLA would therefore recommend that S. 590 be amended to prohibit states from adopting any standards that deviate from the national standards.

Conclusion

In conclusion, ACLA urges this Subcommittee to act promptly on this legislation and to encourage its speedy passage by the Senate. This bill is vitally needed. ACLA will be happy to provide additional information or answer questions at the Subcommittee's pleasure.

STATEMENT  
SUBMITTED BY  
CONSUMER FEDERATION  
OF  
AMERICA  
TO THE  
SUBCOMMITTEE ON  
HEALTH AND SCIENTIFIC RESEARCH  
SENATE COMMITTEE  
ON HUMAN RESOURCES  
RE: S590 THE CLINICAL  
LABORATORY IMPROVEMENTS ACT OF 1979  
MARCH 19, 1979

Consumer Federation of America is a federation of 240 national, state and local non-profit organizations that have joined together to espouse the consumer viewpoint. CFA and its member organizations represent over 30 million consumers throughout the United States. Among our members are: 60 state and local consumer organizations; 83 consumer cooperatives; 16 national labor organizations; and 27 national and regional organizations.

On February 10, 1979, for the fourth consecutive year, the membership of CFA unanimously passed the following resolution urging enactment of the strongest possible Clinical Laboratories Improvements Act:

Consumers have a two-fold interest in establishing standards for clinical laboratory testing: health and cost. Of primary concern is the assurance of strict health and safety standards through reliable clinical testing results.

Consumers are alarmed at the evidence which demonstrates that laboratories including those regulated by Federal law have shocking error rates of most tests ranging from 20 percent to 50 percent. In addition to the human suffering resulting from inadequate clinical laboratory testing, the consumer is forced to bear the high cost of multiple and frequently unnecessary testing. Consumers pay \$12 billion annually for laboratory testing. There are often appalling price differences among laboratories for identical tests.

Accordingly, we urge legislation that would:

- a) Require licensing of all interstate and intrastate clinical laboratories, including independent hospitals and physician office laboratories with collection facilities including blood banks. Unannounced, periodic quality spot-checks should be required;
- b) Permit states to apply more stringent clinical lab standards within allocated federal enforcement functions;
- c) Require disclosure by clinical laboratories of any contractual relationships with physicians, together with a posting of all fees for laboratory testing within local health planning units; and a mandatory itemization of costs on the physicians' statements for services performed;
- d) Require periodic examination of *all* operating personnel. HEW should be required to set up a coordinating unit for that purpose;
- e) Outlaw kickbacks;
- f) Require that advisory committees include an equitable number of bona fide consumer representatives;

g) Require establishment of standards of safe and efficacious methodology so that physicians in clinical laboratories have scientifically recognized evaluations of what tests should be conducted and under what circumstances. Accordingly, tests with marginal or no value should be eliminated; and

h) Encourage medical schools to offer comprehensive courses in clinical laboratory testing.

In addition, the following national consumer, senior citizen, cooperative and labor organizations have, for the past four years, formed a coalition exclusively committed to passage of the Clinical Laboratory Improvement legislation:

Amalgamated Meatcutters and Butcher Workmen  
American Association of Retired Persons  
Communications Workers of America  
Cooperative League of the USA  
International Ladies' Garment Workers' Union  
International Union of Electrical, Radio and Machine Workers  
National Consumers League  
National Council of Senior Citizens  
Retired Employees Department, United Auto Workers of America  
United Auto Workers of America  
United Steelworkers of America

As a matter of humaneness and economics, the need for this legislation is compelling and dramatic. It is unthinkable that Congress delay any longer passage of legislation structured to improve the accuracy and efficiency of this \$12 billion a year industry--an industry that has been exposed in study after study as having intolerable high error rates and patterns of fraud. One HEW study demonstrated that it is likely that at least one out of four laboratory tests are in error. Another study of 200 medicare labs found serious deficiencies in 74% of the labs.

The human and economic costs of the status quo are enormous. When tests fail to detect disease, the eventual result may be exacerbated illness and/or more costly treatment. For example:

- 1) An erroneous lab test result relating to blood sugar level led a physician to prescribe insulin, resulting in the death of the patient. (Kinel v. Hycel, Inc., Illinois City Circuit Court, No. 70 L 241 (Nov. 3, 1973))
- 2) An infant suffered severe brain damage because the erroneous lab test failed to indicate the need for a transfusion. (Schnelby v. Baker, 217 N.W., 2nd 708 (Iowa, 1974))
- 3) A patient suffered invasive cancer as a result of a delay in diagnosis, due to an erroneous test result from an inadequate pap smear. (Cornell v. Clinical Laboratories, California Superior Court, L.A. City Docket No., NCC 3792, June 29, 1975, 25 Citation 163 (1971))

Shoddy lab tests, including the failure to maintain or transport specimens at proper temperature levels, must often be repeated, imposing an additional financial burden on the consumer. Finally, passage of this bill will provide relief to the taxpayer, who picks up these costs in the medicare and medicaid programs. For example, of the \$17 billion 1976 medicare program alone, roughly \$2 billion was spent on lab tests.

Our comments focus primarily on two areas of particular concern: that the coverage of S. 590 be as comprehensive as possible and that there be adequate provisions for consumer involvement in the implementation and enforcement of CLIA. Accordingly, we very much support the inclusion of physicians labs and

## Clinical Labs Statement P. 3

federal, state and local labs. It is felt that the treatment of research labs needs to be strengthened. It does not, however, provide an adequate role for consumers. This could be accomplished by including a provision for Citizen Civil Actions -- a provision of S. 705 which was passed by the Senate unanimously in 1977 -- and a provision to provide public participation reimbursement for proceedings relating to the act.

#### 1. Exemption of Private Physician Labs

CFA strongly supports the inclusion of private physician's labs as provided for by S. 590. CFA vehemently opposes any attempt to remove this provision from the bill or delay inclusion of private physician labs pending an HEW study.

The Consumers' interest and need for accurate, reliable testing is independent of the location in which the test is performed. Indeed, the consequences of faulty testing by physician's labs may oftentimes be greater than for errors made by other clinical labs. Tests in a physician's lab frequently come at the beginning of an illness, when the test result may be the most important element in forming a diagnosis. On the other hand because individual tests in other settings may have less dominance in the patients' case history the physician has a greater likelihood of detecting erroneous results.

Furthermore, the sheer magnitude of tests performed in physician's laboratories is reason enough to be cautious about excluding them from coverage. As the following table indicates, approximately 25% of all lab tests performed in 1975 were performed in private physician's labs:

Estimate of Volume of Clinical Laboratory Tests in 1975

<u>Location of Test</u>	<u>Number in billions</u>	<u>Percent</u>
Private Physicians lab	1.0	25
Independent lab	1.1	27
Hospital lab	1.9	48
Total	4.0	100

Source: Dr. David Kosowsky (Damon Corporation)

This estimate actually understates the involvement of physician labs for two reasons. First, many tests done by hospitals are for monitoring, not diagnostic purposes. Second, many tests done by independent labs are collected by the physician's office.

The most significant national study done to determine the proficiency of private physician laboratories was the 1973 National Bureau of Standards study.<sup>1</sup> This study unequivocally demonstrated that physician office labs were consistently poorer in performance than larger hospital and independent labs. The medical usefulness of the tests were found to be lacking in a large proportion of the tests conducted. Furthermore, as participation was voluntary the results probably understate the problem.

The study identified systematic errors relating to the competency of those performing the tests -- the physician's assistants. The procedures for private physician labs obtaining an exemption (particularly the proficiency testing) provided for in S. 590 would assist the physician in remedying these problems.

Additionally those studies which have focused on private physician labs persuasively demonstrate that: A) high error rates are experienced in physician labs; and B) that the introduction of proficiency testing programs significantly increases the accuracy and reliability of tests.<sup>2</sup> Finally, HEW's call for a study of the problem rather than immediate inclusion of private physician labs rings hollow when it is realized that HEW has been aware of the potential for this leg-

## Clinical Labs Statement P. 4

isolation since 1975, and has not conducted any studies during the intervening four years, nor has it attempted to refute the studies which have already been conducted.

It is also important to note that the vast majority of medical schools provide little, if any, training in laboratory testing. It is imperative, therefore, to assure some sensible degree of accountability.

Periodic proficiency testing is the principal way in which the laboratory director is able to check on and monitor the objective accuracy and reliability of testing. Laboratory proficiency test samples resembling patient specimens are tested and the results are communicated to the laboratory proficiency testing organization. These results are then compared with the true assayed values of the test samples, and the level of accuracy is then observed.

Laboratory proficiency testing is a methodology which has been developed and extensively used by clinical laboratories over the past thirty years. There is no substitute for the objective measure of laboratory performance which periodic laboratory proficiency testing provides. No one today would think of allowing surgery to be performed with unsterilized instruments. Similarly, clinical laboratory testing activities should not be allowed without the objective measure of accuracy and reliability which proficiency testing provides.

Another potentially disturbing aspect of the treatment of physicians' labs is the use of the word routine. Routine should be defined in terms of the potential health and economic consequences of an erroneous test on the patient. Errors on some tests that are commonly performed in physicians offices can significantly alter the diagnosis of a patient. For example, a faulty urinalysis can mean the difference in a diagnosis of a minor urinary infection or serious kidney disease; a faulty CBC can mean the difference between a diagnosis of minor stomach ailments or appendicitis.

Finally, this section should be further strengthened to provide strict penalties for those who falsely obtain exemptions. (As currently worded, anyone found to be falsifying a statement to gain an exemption would only have the exemption revoked).

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Peter W. Finkel, Ted R. Miller, A Proficiency Test Assessment of Clinical Laboratory Capability in the United States. National Bureau of Standards, Washington, DC (NBSIR 73-163), May, 1973.

2

Raymond F. Hain, "Proficiency testing in Oklahoma physicians' office laboratories," The Journal of the Oklahoma State Medical Association, (June, 1970) p.264-268.

Irwin Schoen, G. Thomas and S. Lange, "The quality of performance in physicians' office laboratories," American Journal of Clinical Pathology, 55 (1971) p. 163-170.

William Ulman, Proficiency Testing of Physician's Office Laboratories. Laboratory Division, Connecticut State Department of Health, 1974.



## Clinical Labs Statement p. 5

2. Exemption for Laboratories "Primarily" Engaged in Research

It is essential that the health and welfare of consumers of health care be protected by requiring that all clinical laboratories comply with uniform standards to assure accurate and reliable testing. Tests or procedures which are performed for research, other than research to determine the course of treatment for an individual patient, may safely be exempted from the national standards. When the course of treatment for an individual patient is dependent on the test results, however, the patient's health care should not be put in jeopardy by clinical laboratory testing which does not meet the minimum national standards merely for the reason that those same tests are also used mainly for behavioral or biomedical research. Furthermore, when the patient or the government pays for treatment, the laboratory should meet the national standards.

A particular problem in this area has been the performance of some university labs. In many of the teaching hospitals, research labs perform tests on patients in order to supplement their research income. The effect of this has been to divert work from the main hospital lab (which would be covered by the standards) to the splinter labs. In some cases the consequences for patients has been disastrous. For example, several years ago splinter labs at Johns Hopkins were regularly making such errors as indicating that the patient had TB when this was not the case. Additionally, there are other problems created by the performance of diagnostic test by these "research" labs. First, this process leads to an underutilization of the main lab and a duplication of equipment within the hospital all of which increases costs, which are passed on to consumers and taxpayers. Second, in some instances, these labs will prescribe tests which are useful for the research being conducted but which the patient does not require; yet the patient usually pays. Although it is not known how widespread they are, other abuses include purchase of equipment with NIH funds while passing the cost of the equipment to patients, and requiring unnecessary consultations.

Directors of laboratories which perform both research and clinical testing may argue that the national standards specifying the qualifications of supervisory and laboratory technical personnel do not acknowledge adequately the skills, experience, competence and specialized educational background of research laboratory personnel. If this argument is justified, however, the appropriate resolution of this problem should be achieved through adjusting the standards for personnel qualifications promulgated under the Clinical Laboratory Improvement Act, rather than through an exemption from standards.

Another argument for exemption is that the quality control standards for clinical laboratories are not needed for achieving the research objectives of the laboratory, which are the primary functions of the laboratory. Whether or not the research objectives require such standards should not be the criterion for depriving patients of the assurance that their clinical care is based on accurate and reliable tests conforming to national standards.

Finally, some researchers may argue that the additional cost involved in bringing their laboratories up to national standards will hinder their research, and will impose an unnecessary burden. On the other hand the Bill recognizes the fact that testing in clinical laboratories which do not comply with the national standards can be performed at less expense. In actuality, therefore, skimping on the quality assurance steps necessary to meet national standards would enable the research laboratory to shift resources to research activities. The clinical testing would be subsidizing the research activity. Research would be promoted, therefore, by a purposeful reduction in the quality of clinical testing and an increase in potential hazard for the patient. If such a diversion of resources were done merely for the sake of increasing the net income of the laboratory owner or director, the practice would be condemned. A similar diversion of resources for the sake of subsidizing research is no less worthy of condemnation no matter how laudable the research goals. The diversion of resources from patient safety to research activities cannot be justified.

Clinical Labs Statement p.6

3. Exclusion of State and Federal Clinical Labs

CFA supports S. 590's inclusion of state and federal labs and opposes HEW's attempts to exclude them from the bill's coverage. Again, the consumer's interest and need for accurate and reliable tests is independent of the location of the test. Not only is HEW unable to present any evidence that there is no need for regulation of these labs, the fact of the matter is that the proficiency record of the Indian Health Labs (federal labs) is abysmal.

4. Citizen Civil Actions

As passed by the Senate in 1977, S. 705 provided for citizen civil actions (what would have been section 353 (r) of the Public Health Service Act). CFA believes that this provision is an essential ingredient in effective implementation of S. 590 and is disturbed by its absence in the present bill.

Even under the most sympathetic and conscientious of administrations, government agencies cannot possibly be expected to monitor the potential violations of the mass of federal regulations. For example, in areas of massive unlawful racial discrimination such as in schooling, employment and housing the government will never have the manpower, the techniques or the awareness necessary to enforce the law for all, no matter how hard it tries. Despite good intentions and dedication, the job is just too much to handle. Citizen watchdogs are needed to blow the whistle on violators, and to ensure that the will of Congress is enforced.

Additionally, all too often, the vigorous enforcement of important health, safety, consumer, and environmental regulations is not even attempted when a particular administration is ideologically opposed to such measures. In exercising their discretion as government "prosecutors" and "enforcers" the federal agencies sometimes overlook many violations which the regulated interests would find expensive or bothersome to correct.

Although critics typically argue that the costs of allowing citizens to bring actions to ensure the effective implementation of the act will outweigh the benefits and that frivolous suits will result, the provision in the bill as passed during the 95th Congress precludes such results. Because there is no provision for the award of damages to a successful plaintiff there is no incentive to bring a suit for an economic windfall.

Finally, at a time when public confidence in government remains at disturbingly low levels, this provision will increase confidence by increasing the accountability of the regulatory process.

Clinical Labs Statement p. 7

#### 5. Public Participation in Agency Proceedings

The public has a high stake in the national standards (as well as other regulations required in S. 590) to be promulgated and a legitimate right to participate in the formulation of those standards. Unfortunately, the cost of such participation will be prohibitively high. Accordingly, CFA urges adoption of an additional section to provide reimbursement for public participation in proceedings relating to S. 590.

The language of the amendment precludes the awarding of such participation costs for those who do not make a substantial contribution to the proceedings, or do not have an economic interest that is relatively small in comparison to the cost of participation, or who would have the economic resources to participate effectively even without such an award.

The language of the amendment precludes the awarding of such proceedings, or do not have an economic interest that is relatively small in comparison to the cost of participation, or who would have the economic resources to participate effectively even without such an award.

#### Proposed Amendment:

The Secretary may, pursuant to rules prescribed by him within 120 days after the date of enactment of this act, award reasonable attorneys' fees, expert witness fees, and other costs of participation in a rulemaking proceeding under this subsection to any person if-

(1) the person represents an interest the representation of which will substantially contribute to a fair determination of the proceeding, in light of the number and complexity of the issues presented by the proceeding, the importance of widespread public participation and the need for representation of a fair balance of interest in the proceeding; and

(2)(A) the economic interest of the person is small in comparison to the costs of effective participation in the proceeding by that person, except that if the person is a group or organization, the economic interests of a substantial number of members of such group or organization taken individually are small in comparison to the costs of effective participation in such proceeding, or

(B) the person demonstrates to the satisfaction of the agency that such person does not have sufficient resources adequately to participate in the proceeding in the absence of an award under this subsection in any court action brought under this sub section, the court may award the costs of litigation (including reasonable attorneys' and expert witness fees) to any party if-

(i) the court affords such person the relief sought in substantial measure, or after the filing of such action the agency affords such person the relief sought in substantial measure; and

(ii) (1) the economic interest of the person is small in comparison to the costs of effective participation in the action by that person, except that if the person is a group or organization, the economic interests of a substantial number of members of such group or organization taken individually are small in comparison to the costs of effective participation in such action, or

(11) the person demonstrates to the satisfaction of the court that such person does not have sufficient resources adequately to participate in the action in the absence of an award under this subsection.

#### 6. Records Available to the Public

The ability of citizens to participate in government proceedings and judicial action relating to this act will depend in large part on their ability to have access to the relevant data filed with HEW by clinical laboratories. This should be accomplished by introduction of an amendment that would guarantee that access.

#### 7. Office of Clinical Laboratories

Although in the past CFA has advocated a separate Office of Clinical Laboratories, CFA also supports S. 590 which creates a Director of Clinical Labs. CFA opposes HEW's desire to eliminate this provision. For the Act to have maximum benefit it is essential that a separate Office of Clinical Laboratories or a Director of Clinical Laboratories be created. Not to create a separate office or position runs the serious risk that this important function will be swallowed up in some HEW infra-structure that has neither the interest nor expertise in clinical laboratory testing. When one considers that clinical laboratory testing represents a full 10% of our nation's expenditures for health care, it becomes apparent that it merits the establishment of a specific Office of Clinical Laboratories or a Director.

#### 8. Employee Protection

CFA strongly supports the protections afforded clinical laboratory employees by section 375 (d) but believes that a significant loophole is created in part (2)(A) which states:

"(2)(A) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person in violation of paragraph (1) may, within 60 days after such alleged violation occurs file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor..."

The problem arises because an employee who has been discriminated against may not become aware of it within 60 days of being discriminated against. For example, an employee may be unjustifiably passed over for promotion but may not discover it for many months. Accordingly, we urge that the section be amended to read:

"...within 60 days after the employee knows or reasonably could be expected to have known that such alleged violation occurred file..."

## NEW YORK STATE HEALTH DEPARTMENT

## TESTIMONY ON S. 590

March 16, 1979

We are pleased to have this opportunity to express to your subcommittee the New York State Health Department's views on S. 590, the Clinical Laboratories Improvement Act of 1979.

We in the Department feel that we are well qualified to comment on the proposed legislation, since the Department has had more experience in the improvement of clinical laboratories' performance -- through inspection, testing, and personnel training -- than any other agency or organization in government or out of government.

Almost fourteen years ago, on July 1, 1965, New York became the first state in the nation to initiate a certification and licensing program for clinical laboratories. The enabling legislation was the State's Laboratory Improvement Act, which was enacted by our 1964 Legislature.

Since the law became effective, clinical laboratory performance in the State has greatly improved. The Department sets standards which laboratories have to meet if they are to receive permits to operate. Using innovative proficiency testing procedures, the Department monitors clinical laboratories, offering them the opportunity to demonstrate their ability to perform; if they do not demonstrate that they can meet acceptable standards, a permit is denied or limited. In the first three years of the program, fifty laboratories of a total of about 450 closed because they could not meet State standards.

In 1967, the Federal government used New York's Program as a model for legislation seeking to develop nationwide clinical laboratory standards -- the Clinical Laboratory Improvement Act of 1967. Since 1972, New York has been the only State where clinical laboratories are exempt from Federal inspection under CLIA '67, because it is recognized that our standards are equal to or higher than Federal requirements.

Our regulatory program is carried out by the Health Department's Division of Laboratories and Research. It sets standards for laboratory testing, and inspects, tests and licenses the 268 hospital laboratories and 274 independent laboratories upstate, plus an additional 35 out-of-state laboratories which do business in New York State. The approximately 400 laboratories in New York City are licensed by the City Health Department.

Under State law, directors of all clinical laboratories must hold a Health Department certificate of qualification, and each laboratory must also obtain a yearly operating permit. Health Department inspectors visit each laboratory an average of twice yearly to check on methodology, quality control, staffing, equipment, recordkeeping and general effectiveness.

Proficiency testing is a vital part of our State's laboratory improvement program. The Health Department annually mails and hand-carries sets of test specimens to each clinical laboratory. Each laboratory must analyze the specimens and report its findings on mailed specimens within a specified period. Hand-carried specimens are tested during the laboratory inspector's visits. The tests are designed to measure proficiency in cytogenetics, bacteriology, cytology, hematology, blood banking, clinical chemistry, drug analysis, trace metals and many other testing categories.

Laboratories that fail to meet State standards must improve their proficiency through training and demonstrate it through re-testing, or must cease operation in any categories in which they failed. State-sponsored laboratory training courses in the form of seminars, workshops, and lectures are given as funds permit throughout the State. They are always very well attended, and are in no small way responsible for laboratory improvement.

Most of the laboratory closings have been voluntary. Since the start of the program, we have had to seek legal recourse against only five laboratories. Our aim is not to put laboratories out of business, but actually to assist them in achieving a uniformity and reliability of laboratory testing that is crucial to the diagnosis and treatment of disease.

Human error can never be completely eliminated, but we have come a long way from the 25 to 30 percent inaccurate readings that were common when we began proficiency testing in 1965.

I have reviewed New York State's record at some length to emphasize that the following comments on S. 590 are based on years of experience in the licensing of clinical laboratories, in the course of which the Health Department has acquired much expert knowledge of clinical laboratory regulation.

We believe very strongly that national standards for clinical laboratories, uniformly applied and administered, are essential. This bill would result in the creation of uniform standards, but the mechanism chosen for administering them would not result in their uniform or appropriate application. The Health Care Financing Administration is now administratively responsible (under an interagency agreement) for both Title 18 surveys and surveys of laboratories under CLIA '67. Unfortunately, it has chosen to develop a survey document so vague as to allow different interpretations by different surveyors. This has created such a problem that at least three States, New York, Pennsylvania and California, have developed their own survey documents which allow them to combine Title 18 and State surveys and eliminate interpretation problems. I understand that Pennsylvania has been informally advised that it may not continue to use its checklist for Title 18 surveys. If true, this will cause costly duplication of effort, and is but one example of many which to us indicates that HCFA does not have the technical competence to administer this act for the public good.

Second, we believe that gaining the cooperation of the States is essential to proper administration of this bill. While administering its provisions through the Medicare state agency seems an effective way to accomplish this, we believe that it will have an opposite effect. Most of the issues on which cooperation is important involve either setting or interpreting standards. Our State, and we believe

others as well, has found that HCFA lacks the technical resources to set appropriate standards in the laboratory area. They have also not relied on the resources available at CDC in interpreting standards as they exist.

A recent exchange of correspondence with HEW illustrates some of our concerns with HCFA administration:

In October of 1978, we conducted an inspection of a California laboratory involved in interstate commerce. Serious deficiencies in the cytogenetic laboratory were detected. In addition to notifying the laboratory of these problems, we wrote to Secretary Califano and the California Health Department. We wrote to Mr. Califano because we were concerned, based on the problems found, that the interagency agreement was not working effectively. As you know, the agreement provides that interstate inspections are to be done by Medicare state agencies. We were particularly concerned because the inspected laboratory's staff told us that their cytogenetic department had not been inspected by California surveyors. The response to this letter came from Mr. Edward L. Kelly, acting director of the Office of Standards and Certification in HCFA. His letter, which we consider unresponsive to the issues raised, indicates that HCFA does not understand the difference between a 353(J) and 353(L) agreement under CLIA 1967. Moreover, the letter fails to address the lack of an inspection of the cytogenetics facility. The response from California indicated that cytogenetics does not fall within California laboratory licensure law. This fact, however, does not excuse the total lack of an inspection in this area when the laboratory is engaged in interstate commerce, especially in a medically sensitive area such as cytogenetics.

I have spoken at some length about our concerns with HCFA because we are convinced that this bill will fail in its noble purpose unless some other agency is chosen to administer it. Equally as important, we believe that this bill must provide States qualified to do so with the opportunity to gain primary enforcement responsibility, including responsibility for Title 18 laboratories, if it is to be successfully administered.

There are several other points that we would like to cover very briefly:

Regulation of physicians' office laboratories is a desirable goal. We feel that for it to be effective, there must be discretionary authority for the Secretary to conduct inspections to assure compliance with internal quality control standards.

The concept of uniform standards for all laboratories suggests to us that the insurance laboratory exemption should be deleted and the research laboratory exemption language tightened.

We believe that job-related proficiency and practical examinations for laboratory personnel should be discretionary, not mandatory.

Finally, we believe that all choices of surrogate inspection and testing programs must be left to the States, with the approval of the Secretary, so as to prevent duplication of effort where States apply standards higher than the national ones.

In summary, we support this bill's purpose, but oppose its use of the Medicare administrative system.











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